



September 3rd, 2019

**COMMENTS FROM  
THE NATURAL RESOURCES DEFENSE COUNCIL**

**Glyphosate Proposed Interim Registration Review Decision (PID)  
(Document ID EPA-HQ-OPP-2009-0361-2340)**

We submit these comments on behalf of the Natural Resources Defense Council (NRDC) and our more than 3 million members and activists. NRDC has no fiduciary interest in the topic of these comments, or in any agrochemical.

The Environmental Protection Agency (EPA) continues to put human health and wildlife, including monarch butterflies and critical pollinators, in harm's way from the unnecessary over-use of glyphosate, the main ingredient in glyphosate-based herbicides (GBHs) including Roundup®.

Since the last risk assessment was completed for glyphosate in 1993 its use has skyrocketed, resulting in glyphosate being the most widely used pesticide in the US.<sup>1</sup> In that time, mounting evidence has pointed to adverse human health effects as well as the precipitous decline of the North American monarch butterfly population. Based on the combined data, the EPA needs to severely restrict the use of glyphosate and GBH products immediately.

This spring, April 2019, EPA issued its Proposed Interim Registration Review Decision, PID (Document ID EPA-HQ-OPP-2009-0361-2344).<sup>2</sup> In this document, EPA is proposing label changes it claims will reduce off-target spray drift, and thereby, "reduce the extent of environmental exposure and risk to non-target plants and animals." The document also reaffirms EPA's classification of glyphosate as not likely to cause cancer – a classification that conflicts with the best available science, puts Americans in harm's way, and fails to adhere to EPA's policies and practices. Finalizing the Proposed Interim Decision would violate FIFRA.

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<sup>1</sup> Benbrook CM. Trends in glyphosate herbicide use in the United States and globally. *Environ Sci Eur.* 2016;28(1):3. doi:10.1186/s12302-016-0070-0

<sup>2</sup> Relevant documents can be found on the EPA website here: <https://www.epa.gov/ingredients-used-pesticide-products/proposed-interim-registration-review-decision-and-responses-0>

## OFFICE OF PESTICIDE PROGRAMS TOO 'COZY' WITH MONSANTO

EPA Pesticide Office (OPP) states in the PID that is received over 200 substantive public comments but made no changes to its risk assessments as a result (PID, p. 7). It is a very disappointing disclosure that participation in the public comment process seems to have have no meaningful influence on EPA's assessment of glyphosate.

In contrast to its disregard of public comments, the concerns of the registrant, Monsanto, seem to have been given much closer attention. According to a now-public report by a strategic intelligence firm called Hakluyt, a US domestic policy adviser at the White House 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>3</sup> Such assurances suggest that Monsanto's influence over the EPA risk assessment process is significant, and captures why OPP is treating the public comment process as an empty exercise. Even the Judge in a recent Monsanto court case found the evidence of a "cozy relationship" between Monsanto and EPA employees compelling. The EPA and Monsanto 'coziness' places the public and public interest groups outside of the room, when OPP staff and Monsanto are discussing this pesticide. Moreover, the Hakluyt report also identified an unnamed EPA official with the Pesticide Office that is reported to have said, *"There is growing unease in this office at what seems like scientific intransigence by Monsanto to give credibility to any evidence that doesn't fit their view. We would agree with them that such evidence is non-conclusive, but that does not mean that it is without basis."*<sup>4</sup> This suggests that at least some Pesticide Office staff recognize that Monsanto is not a reliable source of information about the harms of its products, and is instead simply defending its harmful products from criticism and regulatory restrictions.

While it is not unlawful for EPA to meet with outside parties including pesticide registrants, it is unlawful for EPA to make decisions about re-registration or commit to a course of action in meetings with only one party.<sup>5</sup> In a 2005 lawsuit NRDC proved in court that OPP negotiated with Syngenta on regulatory decisions regarding its herbicide atrazine.<sup>6</sup> Such private negotiations compromise ethical and scientific standards and violate the public trust of a federal agency that is charged with protecting human health and the environment. As a federal judge ruled in 2005 in an unrelated pesticide lawsuit, "EPA is not in

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<sup>3</sup> Hakluyt report, Exhibit A, Pilliod v Monsanto, Case No. RG17862702 <https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/05/Monsanto-internal-emails-re-White-House-July-2018.pdf>

Also reported in The Intercept here: <https://theintercept.com/2019/08/23/monsanto-republicans-cancer-research/>

<sup>4</sup> Hakluyt report, Exhibit A, Pilliod v Monsanto, Case No. RG17862702 <https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/05/Monsanto-internal-emails-re-White-House-July-2018.pdf>

<sup>5</sup> In 1983, NRDC and others filed a lawsuit alleging that the pesticide industry was exerting improper, secret influence on EPA's decision-making in the pesticide registration process. In 1984, the parties entered into a Settlement Agreement that required EPA to develop regulations to open the registration process. NRDC v. EPA, No. 83-1509 (D.D.C. Sept. 20, 1984); 40 C.F.R. Parts 154 and 155). 1983

<sup>6</sup> Sass JB, Colangelo A. European Union bans atrazine, while the United States negotiates continued use. Int J Occup Environ Health. 2006 Jul-Sep;12(3):260-7. <https://www.ncbi.nlm.nih.gov/pubmed/16967834>

the business of reaching consensus with the ‘stakeholders’ it regulates. EPA’s job is independent review”.<sup>7</sup>

The public and public interest groups including NRDC have a right to expect that EPA will follow its legal requirements to fully consider comments submitted to the docket during public comment periods and incorporate information and recommendations as appropriate.

Monsanto, now Bayer’s, goals are to: support glyphosate registration and approval worldwide; defend itself against litigation claims by farmers who were once Monsanto customers and are now cancer patients; and, prevent labeling of glyphosate-containing products as containing a carcinogen in the State of California and everywhere else. The mission of EPA is to protect human health and the environment. EPA cannot do this if it is ‘cozy’ with the industries it is supposed to regulate, so that its regulatory priorities and health concerns are dictated by corporations like Monsanto and Bayer that have a financial stake in weakening and avoiding regulatory restrictions and hazard assessments that increase its liability.

## HUMAN HEALTH RISKS

### EPA Cancer Experts say OPP is misapplying EPA Cancer Guidelines

EPA’s revised cancer assessment was finalized in December 2017.<sup>8</sup> Since then, there has been some new and updated scientific studies published, as well as two more recent meta-analyses that include the new studies. These all identify cancer risks associated with exposure to glyphosate and GBH products. Yet, EPA continues to defend its classification of glyphosate as, “not likely to be carcinogenic to humans”. In the Glyphosate PID, OPP states that its classification is based on a “thorough weight-of-evidence review” in accordance with its 2005 Guidelines for Carcinogen Risk Assessment (PID, p. 7-8). However, EPA Office of Research and Development (ORD) cancer experts appear to disagree with OPP’s classification of glyphosate and its application of the Cancer Guidelines. An EPA internal memo from ORD scientists recommend that EPA categorize the totality of evidence - epidemiology, animal toxicology and mechanistic data - as either ‘likely’ or ‘suggestive’ of a link with cancer. The memo specifically states that a classification of ‘not likely’ is inappropriate.<sup>9</sup> The ORD memo also describes what must have been a very frustrating conversation between ORD epidemiologists and OPP (OPP does not have any epidemiologists on staff) in which ORD, “tried to communicate this nuanced evaluation of the epidemiology” (whether to classify as likely or suggestive of causing cancer) to OPP, without success. ORD writes that, “OPP insisted on dichotomizing this to be either ‘causal’ or ‘not causal’. The dichotomization is a major factor in the different positions”.<sup>10</sup> In other words, OPP is not considering all of its five cancer classification options under the EPA Cancer Guidelines – including likely, suggestive,

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<sup>7</sup> West Harlem Environmental Action v. EPA , 2005 WL 1863187 at \*7, Civ. No. 04-8858 (S.D.N.Y. 2005). 2005

<sup>8</sup> Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, available in the glyphosate public docket (EPA-HQ-OPP-2009-0361).

<sup>9</sup> EPA 2015. Memo from Vincent Cogliano, ORD to Norman Birchfield re: Glyphosate follow up. December 7, 2015. <https://assets.documentcloud.org/documents/4641115/Cogliano-Memo.pdf>

<sup>10</sup> EPA 2015. Memo from Vincent Cogliano, ORD to Norman Birchfield re: Glyphosate follow up. December 7, 2015. <https://assets.documentcloud.org/documents/4641115/Cogliano-Memo.pdf>

and inadequate evidence – and is instead acting as if its only choices are ‘known’ or ‘not likely’ to cause cancer in humans.

**EPA’s Science Advisory Panel: OPP cancer assessment is biased, misrepresenting science, dismissing cancer evidence**

In its March 2017 report, the Agency’s Science Advisory Panel (SAP) identified important ways in which OPP wrongly dismissed published scientific studies linking glyphosate exposure to non-hodgkins lymphoma (NHL) cancer in people. However, EPA ignored the SAP report, instead repeating the same false and misleading statements in its Revised cancer assessment (EPA Dec 2017).

For example, the SAP report states, “In the report, the Agency stated that the direction of confounding is to inflate any true effect of glyphosate in the absence of statistical adjustment. The Panel noted that this is not always true, and that numerous studies have shown that the effect of confounding can be in either direction” (SAP, p.29). However, in its December 2017 Revised cancer assessment, EPA includes the same statement, unchanged: “As a result, the direction of confounding would be to inflate any true effect of glyphosate in the absence of statistical control”.<sup>11</sup> (EPA 2017, p. 29) This issue is not trivial, since EPA is talking specifically about confounding from other pesticides that virtually all farmers and pesticide applicators are exposed to. EPA is using this statement to cast doubt and ultimately to wrongly dismiss the entire body of epidemiologic evidence of cancer in people. In fact, EPA does exactly that in its Revised cancer assessment when it includes as its reasons for dismissing a “suggestive evidence” classification that, “two-case [sic] control studies did not account for co-exposure to other pesticides, which would be expected to cause inflated effect estimates.” (EPA 2017, p. 141) This is a false and misleading representation of the data that fails to follow scientific best practices.

In another example, SAP chastised the EPA for mis-characterizing the meta-analyses showing elevated NHL risks as non-statistically significant, when “in fact, all three meta-analyses show statistically significant” elevated risks of NHL (SAP, p. 43). The SAP report presents lengthy discussions of this problem and includes suggestions to present the data in a more accurate fashion (SAP, p. 43-45). The SAP even included an overview Table of all the studies (SAP, p. 45). The SAP report specifically notes that some Panel members felt that EPA’s discussion of the epidemiologic evidence was “highly imbalanced”, focusing on weaknesses and limitations in studies, failing to present the perspective that the evidence was suggestive of a link with NHL, and biasing discussions to “down-weight statistical findings and up-weight non-statistical criteria” (SAP, p. 46). And yet, the opening sentence in the EPA 2017 Revised assessment that discusses the NHL epidemiology data states, “With respect to meta-analyses, caution should be taken when interpreting results.” (EPA 2017, p. 64). EPA goes on for several pages emphasizing the study limitations, bias and confounding without providing any discussion of the strengths of a meta-analysis. Most egregious, EPA hand-waves away the evidence linking glyphosate to NHL cancer risk by saying the evidence isn’t strong enough, calling the statistical significance “borderline” and “just slightly over 1” (EPA 2017, p. 64). Plain and simple, this is a completely inappropriate misuse of statistics, and fits that old trope of using statistics more like a drunk uses a lamppost, for support rather than illumination.

Ultimately, EPA ends this section by concluding that “due to study limitations and contradictory explanations for observed associations [that is, evidence of cancer risk]” EPA cannot determine whether

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<sup>11</sup> Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, available in the glyphosate public docket (EPA-HQ-OPP-2009-0361).

there is an association between glyphosate exposure and NHL cancer risk (EPA 2017, p. 68). This is a biased discussion, leading to a biased and erroneous conclusion.

The SAP report notes that, “it would be inappropriate for EPA to conclude that the studies produced contradictory findings, as was done on page 68” (SAP, p. 46). Yet, EPA’s Revised assessment does exactly that, dismissing positive cancer findings in epidemiologic studies because other studies did not find a link to cancer (EPA 2017, p. 141).

OPP is failing to follow established scientific practices in its glyphosate cancer assessment, instead presenting biased analyses that support false claims of safety.

**Science Advisory Panel disagree with the Pesticide Office, says evidence supports a ‘suggestive’ link to cancer**

The PID states that, “although the SAP did not reach a consensus” (which is true) “none of the panelists” recommended that it be classified in the two highest categories, ‘carcinogenic’ or ‘likely’ to cause cancer in humans (PID p. 7). However, there are five cancer classifications in the EPA Cancer Guidelines, and although the SAP did not recommend the first two categories, it also did not support OPP’s choice of the last category. In fact, the SAP report presents lengthy discussions on Panel members that disagreed with EPA’s conclusions, resulting in a two-page detailed summary called, “Disagreeing with the Conclusion” (SAP, p. 47-48). Those Panel members felt that the evidence linking glyphosate to elevated risk of NHL cancer was “suggestive”, and recommended that OPP revise its conclusions to use the following statement, “Based on the weight-of-evidence from all available data that were abstracted from all qualified human studies, the Agency cannot exclude the possibility of observed positive associations between glyphosate exposure and risk of NHL suggesting human carcinogenic potential of glyphosate even though study limitations and concerns about potential biases remain.” (SAP, p. 48). In short, OPP’s cancer classification of glyphosate is not supported by either the scientific evidence or by the SAP – it is the result of a biased misleading or false interpretation of the evidence.

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| <p>EPA Cancer Guidelines classifications:</p> <ol style="list-style-type: none"> <li>1. Carcinogenic to humans;</li> <li>2. Likely to be carcinogenic;</li> <li>3. Suggestive evidence of carcinogenic potential;</li> <li>4. Inadequate information to assess carcinogenic potential;</li> <li>5. Not likely to be carcinogenic to humans.</li> </ol> |
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**New science of harm**

***Zhang et al (2019) – further confirms NHL cancer risk***

This year three of the epidemiologists that had served on the SAP (Drs. Zhang, Taioli, and Sheppard) co-published a glyphosate cancer meta-analysis. This updated analysis includes additional data from the updated Agricultural Health Study (Andreotti et al 2018). The Zhang et al (2019) meta-analysis reported the overall relative risk of NHL cancers in people exposed to GBHs was increased by 41% above background (meta-RR=1.41, 95% confidence interval CI, 1.13-1.75).<sup>12</sup> This means that after pooling all of the available studies using appropriate statistical methods the data show that exposure to GBH products will increase the risk of getting NHL by 13% to 75%. The authors add that both the rodent studies and

<sup>12</sup> Zhang L, Rana I, Shaffer RM, Taioli E, Sheppard L. Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence. *Mut Res/Rev Mut Res*, 781:186-206. <https://doi.org/10.1016/j.mrrev.2019.02.001>

mechanistic data are consistent with this conclusion, and therefore increase our confidence that glyphosate causes cancer. The study also documents that mice treated with pure glyphosate had an increase in malignant lymphoma. The study authors conclude that, “overall, in accordance with evidence from experimental animal and mechanistic studies, our current meta-analysis of human epidemiological studies suggests a compelling link between exposures to GBHs and increased risk of NHL”.<sup>13</sup> This report should be considered to be the updated conclusions of three of the SAP experts, and is consistent with their SAP comments, and with health agencies including the 2019 ATSDR assessment (see below) and the 2015 IARC assessment.

The risk estimates reported by Zhang et al (2019) are almost identical to those reported by IARC (2015) and in a Monsanto-sponsored meta-analysis by Chang and Delzell (2016)<sup>14</sup>, all of which report a statistically significant increased risk of NHL associated with exposure to GBH products:

Study author (year)	Relative Risk of NHL	95% CI
Schinassi and Leon (2014) <sup>15</sup>	1.45	1.08, 1.95
IARC (2015)	1.30	1.03, 1.64
Chang and Delzell (2016)	1.27	1.01, 1.59
Zhang et al (2019)	1.41	1.13, 1.75

These published reports show an impressively high level of agreement between meta-analysis results, ranging from the World Health Organizations cancer experts at IARC to Monsanto-sponsored researchers. The conclusions across all these studies is also in agreement with the EPA ORD cancer experts described in the memo, and the SAP members that felt there was ‘suggestive’ evidence of a link to cancer. In short, putting aside whether the risk is strong (a higher RR value) or weak (a lower RR value), there is a link and that it is statistically significant.

#### ***ATSDR 2019 – further confirms NHL cancer risk***

This past spring the Agency for Toxic Substances and Disease Registry (ATSDR), housed in the Centers for Disease Control and Prevention (CDC) issued a report that also link glyphosate to cancer.<sup>16</sup> The ATSDR report clearly lays out the vast array of scientific evidence linking both pure glyphosate (rodent studies) as well as formulated glyphosate-containing products (in human epidemiologic studies) like Roundup as they are sold on the shelf to cancer. A summary of the major findings are as follows:

Epidemiological evidence of NHL from exposure to GBH products (ATSDR, p. 86, Fig 2-4):

<sup>13</sup> Zhang L, Rana I, Shaffer RM, Taioli E, Sheppard L. Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence. *Mut Res/Rev Mut Res*, 781:186-206. <https://doi.org/10.1016/j.mrrev.2019.02.001>

<sup>14</sup> Chang ET, Delzell E. Systematic review and meta-analysis of glyphosate exposure and risk of lymphohematopoietic cancers. *J Environ Sci Health B*. 2016;51(6):402-34. doi: 10.1080/03601234.2016.1142748.

<sup>15</sup> Schinasi L, Leon ME. Non-Hodgkin lymphoma and occupational exposure to agricultural pesticide chemical groups and active ingredients: a systematic review and meta-analysis. *Int J Environ Res Public Health*. 2014 Apr 23;11(4):4449-527. doi: 10.3390/ijerph110404449

<sup>16</sup> ATSDR Toxicological Profile for Glyphosate Draft for Public Comment March 2019, Docket No. ATSDR-2019-0001

- The association with non-Hodgkin Lymphoma (NHL) cancer risk is stronger when the study is adjusted for more days of glyphosate use, longer study latency period (time since exposure for cancer to develop), which strengthens the confidence in the results;
- All three meta-analyses (evaluation of many studies together) show a statistically significant link with NHL cancer (positive confidence intervals), with narrow confidence intervals which strengthens our confidence in the link with cancer. This is true even of the Monsanto-sponsored analysis (Chang and Delzell, 2016), which is almost exactly the same result as the conclusions of the World Health Organization's global cancer experts (IARC 2016).
- Most studies are strongly positive for cancer (non-Hodgkin's Lymphoma), even if they are not statistically significant at a 95% confidence level. All would likely show a statistically significant link with cancer at a 90% confidence level.

### ***ATSDR 2019 – acute and chronic non-cancer health effects***

There are significant non-cancer adverse effects that EPA must also consider in its risk evaluation. ATSDR reviewed high-quality studies that reported a number of non-cancer acute and chronic health effects (Chapter 2, Health Effects):

- ATSDR identifies scientific evidence in rodent studies and some human epidemiologic studies linking glyphosate with gastrointestinal effects including nausea and vomiting, kidney and liver toxicity, and eye irritation (ATSDR summary data p. 3-5).
- Long-term ongoing health studies conducted by the U.S. National Cancer Institute of over 20 thousand pesticide applicators report that human exposures to glyphosate-containing products is linked to an elevated risk of wheezing, chronic bronchitis, and allergic asthma (ATSDR, Table 2-5, p. 36; Ag Health Study)

These data provide a basis for a database uncertainty factor of at least 10X, to account for the non-cancer acute and chronic health effects that these studies identify, from exposure to glyphosate and GBHs.

### ***ATSDR 2019 – data gaps supports FQPA of at least 10X***

EPA's PID states that there are "no human health data needs", that EPA has all the human health data that it requires for the registration review, and that the Data Call-In (DCI) has been satisfied for human health data (PID, p. 25). However, many critical human health endpoints were identified by ATSDR in its review as lacking important information. These are discussed in Chapter 6 of the ATSDR report, where 'Adequacy of the Database' is discussed (ATSDR, p. 159-166). Data needs are identified as follows:

- For glyphosate technical (the pure a.i.), there are no studies on respiratory effects, cardiovascular effects, and endocrine effects (ATSDR, p. 160). There is only one study in immunological effects, and dermal effects. There are also no inhalation exposure studies.
- For Glyphosate formulation products (GBHs), almost all the toxicity studies are from human population exposures, mainly for cancer, cardiovascular, gastrointestinal, respiratory, and developmental effects (ATSDR, p. 161). ATSDR identifies about fifty studies, none of which are used by EPA to quantify human health risks.
- There are almost no studies on GBH formulated products in animals, by either inhalation or oral exposure routes of exposure (ATSDR, p. 161).

- There are no inhalation Minimal Risk Level values (MRL) for glyphosate, due to the lack of quantitative exposure-response data from either human or animal studies (ATSDR, p. 162). This lack of data extends across acute, intermediate, and chronic duration exposures.
- There is only limited information on the effects of inhalation exposure, based on a single 4-week rodent study with Roundup (ATSDR, p. 163).
- There are no toxicokinetic studies on inhaled glyphosate or GBHs (ATSDR, p. 164).
- There are no studies on children’s susceptibility to either glyphosate or GBHs. These include a lack of studies on age-related differences in susceptibility (ATSDR, p. 164).
- Additional studies on glyphosate persistence in foods, water, and soil are needed (ATSDR, p. 165), to evaluate the environmental fate.
- “Studies are needed to investigate the human intake of glyphosate via food and water, such as total diet studies” (ATSDR, p. 165). This data gap is largely because up until 2016-17 the FDA did not test for glyphosate residues in food or drinking water.

In addition to the above data needs, the ATSDR identified ongoing studies that it suggests would be useful to inform EPA’s human health risk assessment. These include genetic and toxicity studies on glyphosate and GBHs from the National Toxicology Program, as well as Ramazzini Institute studies on the genetic reproductive, and developmental effects of glyphosate and GBHs in rodents at human-relevant exposure doses (ATSDR, p. 166).

**ATSDR 2019 – developmental harm supports FQPA of at least 10X**

ATSDR identified developmental effects from early life exposures, as follows:

- Developmental risks reported in studies of farm families identify a link between parental use of glyphosate and an increased risk of neural tube defects, miscarriage, preterm delivery, and small for gestational age (ATSDR Table 2-5, p. 40-41).
- ATSDR summarizes a number of animal studies of early-life exposure to GBHs that report developmental effects including testicular lesions, decreased sperm production, elevated abnormal sperm, decreased testosterone, and skeletal malformations (ATSDR, p. 14).

These data provide a basis for an FQPA factor of at least 10X, to address the very serious developmental effects that these studies identify, from exposure to glyphosate and GBHs.

Also supporting an FQPA factor of at least 10X, the ATSDR reviewed all available studies relevant to age- or gender-related differences in susceptibility to toxic effects from glyphosate and the formulated products (ATSDR p. 116):

- ATSDR identified an important high-quality recent study by Panzacchi et al (2018) that exposed pregnant rats (F0) to drinking water laced with glyphosate or a Roundup formulated product from Gestational Day (GD) 6 through lactation, and then to their offspring to postpartum day 125; doses were calculated to be 1.75 mg/kg-day (study design, Panzacchi et al, 2018).<sup>17</sup> The disturbing result is that the gut microbiome – an essential component of health growth, nutrition absorption, immunity, and other necessary functions -was altered in the F1 pups but

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<sup>17</sup> Panzacchi S, Mandrioli D, Manservigi F, Bua L, Falcioni L, Spinaci M, Galeati G, Dinelli G, Miglio R, Mantovani A, Lorenzetti S, Hu J, Chen J, Perry MJ, Landrigan PJ, Belpoggi F. The Ramazzini Institute 13-week study on glyphosate-based herbicides at human-equivalent dose in Sprague Dawley rats: study design and first in-life endpoints evaluation. *Environ Health*. 2018 May 29;17(1):52. doi: 10.1186/s12940-018-0393-y. PubMed PMID: 29843719; PubMed Central PMCID: PMC5972408.

not animals that were treated only as adults.<sup>18</sup> The authors conclude that, “This study provides initial evidence that exposures to commonly used GBHs, at doses considered safe, are capable of modifying the gut microbiota in early development, particularly before the onset of puberty. These findings warrant future studies on potential health effects of GBHs in early development such as childhood”.<sup>19</sup> This study demonstrates the potential for age-related susceptibility, and is especially concerning given that the microbiome impacts may have long-term or even lifetime adverse effects on growth, health, and development. Studies have linked age-dependent changes in gut microbiota to altered immune, neuroendocrine, and nerve cell development.<sup>20</sup> In short, these data suggest that neurodevelopmental effects including brain structure and function may be altered by early-life exposure to glyphosate and GBHs.

- An earlier rodent study (Romano et al, 2010) reported that juvenile male rats exposed by gavage to a commercial GBH product at levels as low as 5 mg/kg-day during puberty had decreased testosterone levels. (ATSDR, p. 116).<sup>21</sup>

The available evidence from the published peer-reviewed scientific literature demonstrates a potential early life susceptibility to glyphosate exposure, with possible severe and lifelong effects. These studies, and the uncertainty given that there are no long-term outcome studies, support the use an FQPA adjustment factor of no less than 10X, as required by law.

### **Inappropriate interventions by OPP staff on behalf of Monsanto to “kill” the ATSDR assessment**

Internal emails and documents from several years ago have now come to light through court proceedings. These documents indicate that OPP staff and Monsanto appear to have coordinated work to block ATSDR’s glyphosate assessment.<sup>22</sup> A point-form summary of OPP efforts, with links to the original documentation in the footnote, is here:

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<sup>18</sup> Mao Q, Manservigi F, Panzacchi S, Mandrioli D, Menghetti I, Vornoli A, Bua L, Falcioni L, Lesseur C, Chen J, Belpoggi F, Hu J. The Ramazzini Institute 13-week pilot study on glyphosate and Roundup administered at human-equivalent dose to Sprague Dawley rats: effects on the microbiome. *Environ Health*. 2018 May 29;17(1):50. doi: 10.1186/s12940-018-0394-x. PubMed PMID: 29843725; PubMed Central PMCID: PMC5972442.

<sup>19</sup> Mao Q, Manservigi F, Panzacchi S, Mandrioli D, Menghetti I, Vornoli A, Bua L, Falcioni L, Lesseur C, Chen J, Belpoggi F, Hu J. The Ramazzini Institute 13-week pilot study on glyphosate and Roundup administered at human-equivalent dose to Sprague Dawley rats: effects on the microbiome. *Environ Health*. 2018 May 29;17(1):50. doi: 10.1186/s12940-018-0394-x.

<sup>20</sup> Foster JA, McVey Neufeld KA. Gut-brain axis: how the microbiome influences anxiety and depression. *Trends Neurosci*. 2013;36:305–12.

Heijtz RD, Wang S, Anuar F, Qian Y, Bjorkholm B, Samuelsson A, et al. Normal gut microbiota modulates brain development and behavior. *Proc Natl Acad Sci*. 2011;108:3047–52.

Koloski NA, Jones M, Kalantar J, Weltman M, Zaguirre J, Talley NJ. The brain–gut pathway in functional gastrointestinal disorders is bidirectional: a 12-year prospective population-based study. *Gut*. 2012;61:1284–90.

Carabotti M, Scirocco A, Maselli MA, Severi C. The gut-brain axis: interactions between enteric microbiota, central and enteric nervous systems. *Ann Gastroenterol*. 2015;28:203–9.

Liang S, Wang T, Hu X, Luo J, Li W, Wu X, et al. Administration of *Lactobacillus helveticus* NS8 improves behavioral, cognitive, and biochemical aberrations caused by chronic restraint stress. *Neuroscience*. 2015;310:561–77.

<sup>21</sup> Romano RM, Romano MA, Bernardi MM, Furtado PV, Oliveira CA. Prepubertal exposure to commercial formulation of the herbicide glyphosate alters testosterone levels and testicular morphology. *Arch Toxicol*. 2010 Apr;84(4):309-17. doi: 10.1007/s00204-009-0494-z.

<sup>22</sup> <https://usrtk.org/tag/mary-manibusan/>

- The head of the OPP Glyphosate Cancer Assessment Review Committee (CARC), Jess Rowland, is reported in an internal corporate memo from Monsanto as saying to Monsanto that if he can “kill” the ATSDR report then he should “get a medal” (April 2015).<sup>23</sup>
- In response to an email from Monsanto, Jim Jones instructed OPP Director Jack Housenger to contact ATSDR (May 2015). At that time, Jim Jones was the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP), which has oversight of OPP.
- At the direction of his manager, Jim Jones, Housenger emailed ATSDR leadership to ask whether ATSDR still felt, “the need to do your assessment”, given that OPP’s was well underway (May 2015),<sup>24</sup> and in a follow-up email that it would be a, “duplicative government effort” (June 2015).<sup>25</sup> Neither Housenger nor anyone else at OPP appears to disclose to ATSDR that OPP’s request began with Monsanto.
- When ATSDR rebuffed OPP’s requests, Monsanto reached out to Mary Manibusan to ask if she knew folks at ATSDR that could help. At the time, Manibusan was working with the industry consulting firm Exponent, but had previously been an OPP toxicologist. Manibusan sent back a message to Monsanto, “Sweetheart- I know lots of people. You can count of [sic] me” (June 2015).<sup>26</sup> Manibusan has now re-joined EPA.

Additional exchanges, details, and links to original documents are all provided to the public online at U.S. Right To Know (USRTK).<sup>27</sup>

Monsanto corporate documents indicate that the maneuver was successful; Monsanto reports that, “CDC’s Agency for Toxic Substances and Disease Registry announced one year ago that it would also assess glyphosate’s toxicity and cancer potential in parallel with EPA. They have agreed, for now, to take direction from EPA.”<sup>28</sup> In the same internal memo, Monsanto writes that, “We know, *but cannot say*, that EPA’s Office of Pesticide Program scientists strongly feel that glyphosate does not cause cancer and have defended their written determination internally for months”.<sup>29</sup> So, its corporate communications seem to show that Monsanto had assurances that it could expect an OPP assessment to be favorable to glyphosate’s continued sales.

Monsanto was right to be concerned that ATSDR’s assessment would not align with OPP, and was likely to identify cancer risks. However, EPA is a federal agency, funded by the public purse, and charged with implementing its regulatory authorities in a manner that protects human health and the environment. Interfering in the work of a sister health agency is very concerning; doing so on behalf of the agrochemical corporations that it is supposed to regulate is an outrageous abdication of its duties to the public including

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<sup>23</sup> Pl.’s Mot. to Compel the Dep. of Jess Rowland at page 101-103, In re Roundup Products Liability Litigation, No. 3:16-MD-02741 (N.D. Cal. Mar. 14, 2017), ECF No. 189. <https://www.documentcloud.org/documents/3521387-Doc-189-Docs-Mentioning-EPA-Jess-Rowland.html>

<sup>24</sup> <https://usrtk.org/wp-content/uploads/2017/08/May-20-2015-Breyse-ATSDR-on-EPA-request.pdf>

<sup>25</sup> <https://usrtk.org/wp-content/uploads/2017/08/June-6-2015-EPA-ATSDR.pdf>

<sup>26</sup> <https://usrtk.org/wp-content/uploads/2017/08/Text-Messages.pdf>

<sup>27</sup> <https://usrtk.org/tag/mary-manibusan/>

<sup>28</sup> Pl.’s Mot. to Compel the Dep. of Jess Rowland at page 107, In re Roundup Products Liability Litigation, No. 3:16-MD-02741 (N.D. Cal. Mar. 14, 2017), ECF No. 189. <https://www.documentcloud.org/documents/3521387-Doc-189-Docs-Mentioning-EPA-Jess-Rowland.html>

<sup>29</sup> <https://baumhedlundlaw.com/pdf/monsanto-documents-2/Memo-re-EPA-influence-for-defending-glyphosate.pdf>

farmers, farmworkers, pesticide applicators and their families who are frequently exposed to dangerous pesticidal products.

### **NRDC opposes non-pesticide uses of glyphosate and other herbicides as a pre-harvest desiccant**

NRDC requests that OPP cancel the use of glyphosate and other herbicides as pre-harvest desiccants (called 'green burndown') on food crops. These uses – increasingly popularized since the mid-2000's – have been the cause of rising levels of glyphosate residues in foods, including many that are favorites of children and women of reproductive age, such as oat-based breakfast cereals and snack bars.

Unfortunately, OPP's response has been to increase the tolerances limits for glyphosate. In an FR notice published in Spring, 1997<sup>30</sup> OPP stated:

- The Agency has decided that only glyphosate parent is to be regulated in plant and animal commodities and that the major metabolite, AMPA (aminomethylphosphonic acid) is not of toxicological concern regardless of its levels in food;
- Since no U.S. registration has been proposed for oats, it has been concluded that oat feed items are not likely to enter channels of trades in the United States;
- [Maximum Residue Limits] MRL's of 20 ppm, 10 ppm, and 0.1 ppm on oats are established/pending for CODEX, Canada, and Mexico, respectively.
- The increased tolerances now being proposed on corn and sorghum are based on new preharvest uses of glyphosate in the United States. The import tolerance being proposed for oats is being proposed to harmonize with other international MRL's

This dangerous ramping up of glyphosate uses, especially on food crops, is proved to lead directly to human exposures. That is why the Environmental Working Group and food and nutrition companies including MegaFood, Ben & Jerry's, MOMs Organic Market, and Stonyfield Farm, petitioned EPA to ban the preharvest use of glyphosate on oats as a desiccant on oats.<sup>31</sup>

NRDC supports the petition request to cancel all preharvest uses of glyphosate – it is based on scientific evidence that GBH products cause harm, and that desiccant uses lead to exposures to Americans including the most susceptible age groups, infants, children and women of reproductive age.

OPP says it is still reviewing the petition, and intends to respond when it issues its the Interim Registration Review Decision for glyphosate.<sup>32</sup> OPP states that it will treat the petition as a public comment on this PID (PID, p. 6). Meanwhile, these unsafe uses are continuing to put American's food supply at risk. OPP should respond as quickly as possible to grant the petition, and cancel these uses.

### **Endocrine disruption – supports FQPA 10X**

EPA states that it has not completed an endocrine screening assessment for glyphosate, as required under the FFDCFA Section 408, before completing registration review (PID, p. 3). EPA subjected

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<sup>30</sup> FR April 11, 1997 (Volume 62, Number 70)] Page 17723-17730  
[https://www3.epa.gov/pesticides/chem\\_search/reg\\_actions/reregistration/tred\\_PC-417300\\_11-Apr-97.pdf](https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/tred_PC-417300_11-Apr-97.pdf)

<sup>31</sup> Petition to Modify the Tolerance of Glyphosate in Oats to 0.1 ppm and Require Glyphosate-Containing Product Labels to Explicitly Prohibit the Use of Glyphosate as a Preharvest Desiccant. Document ID EPA-HQ-OPP-2019-0066-0002.

<sup>32</sup> The agency is still reviewing this petition and has issued a Federal Register Notice of Filing for public comment in docket EPA-HQ-OPP-2019-0066

glyphosate to its Tier 1 assessment under the EPA Endocrine Disruptor Screening Program (EDSP). Based on that battery of in vitro tests, EPA determined that there was no convincing evidence of potential interactions between glyphosate and estrogen, androgen, or thyroid pathways (EPA 2015). EPA's 2015 determination is based entirely on its in vitro suite of studies, submitted by the registrant.

However, there is evidence of endocrine disruption activity in the non-industry peer reviewed published scientific literature. A rodent study reported that rats exposed to GBHs from pre-birth to a week after birth (GD18 to PND5) resulted in male offspring with altered masculinization and behavioral changes associated with an elevated level of male hormone (androgen) activity (Romano et al 2012; ATSDR, p. 116).<sup>33</sup> The proposed mechanism of action for glyphosate disruption of male sexual development is an endocrine disruption pathway of reduced gonadotropin expression (Romano et al 2012; ATSDR p. 50).

A 2019 collaborative study from researchers in Italy, Brazil, Denmark, and in the US at the George Washington University, Mount Sinai School of Medicine reported on endocrine disruption effects in male and female mice exposed to glyphosate and GBHs from pre-birth (GD6) to after puberty (PND120).<sup>34</sup> This important study reported endocrine effects in both male and female animals. Anogenital distance (AGD), which is a sex-specific characteristic (males have a longer distance, females have a shorter distance) was increased in males (glyphosate group) and females (GBH group), suggesting that it has a masculinizing effect on reproductive development. In females, the age at first estrus (puberty) was significantly delayed (GBH group). In the group exposed for a shorter length of time (6-week cohort), hormone alterations only occurred in males, not females; males were affected by both glyphosate and GBH, which increased levels of thyroid hormones (TSH) and a brain growth factor (BDNF). In the cohort treated for longer (13-week cohort), sex steroid hormone levels were altered in both sexes from GBH exposure, but not exposure to glyphosate alone. The researchers warn that these data suggest that glyphosate and GBHs is an Endocrine Disrupting Chemical (EDC), and through an endocrine disruption mechanism lead to reproductive system toxicity. They also point out sex differences in the toxicological response to glyphosate and GBHs, which is frequently observed with EDCs.

There is scientific evidence from global experts that glyphosate and GBHs may cause endocrine disruption, that there may be age- and sex-specific differences in the observed adverse effects, and that reproductive development may be a particularly sensitive target system. Some of this evidence is so recent that it has not been considered by EPA or ATSDR in its report. This evidence strongly supports an FQPA factor of at least 10X.

### **Dietary exposures unsafe**

EPA determined that children 1-2 years old are considered the most highly exposed subpopulation for residential and non-occupational settings, with oral exposures from dietary (food and water) ingestion

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<sup>33</sup> Romano MA, Wisniewski P, Viau P, Romano RM, Campos DA, Bernardi MM, et al. Glyphosate impairs male offspring reproductive development by disrupting gonadotropin expression. *Arch Toxicol.* 2012;86:663–73.

<sup>34</sup> Manservigi F, Lesseur C, Panzacchi S, Mandrioli D, Falcioni L, Bua L, Manservigi M, Spinaci M, Galeati G, Mantovani A, Lorenzetti S, Miglio R, Andrade AM, Kristensen DM, Perry MJ, Swan SH, Chen J, Belpoggi F. The Ramazzini Institute 13-week pilot study glyphosate-based herbicides administered at human-equivalent dose to Sprague Dawley rats: effects on development and endocrine system. *Environ Health.* 2019 Mar 12;18(1):15.

and incidental oral ingestion (e.g., hand-to-mouth activities) in treated areas.<sup>35</sup> There is also potential for dermal exposures in previously treated areas.<sup>36</sup>

Deep within EPA's 2017 Revised cancer assessment is this summary of EPA's aggregate exposure assessment for children:

"The highest dietary exposure value for any population subgroup in an unrefined chronic dietary analysis would be 0.23 mg/kg/day for children (1-2 years old). Since glyphosate also has residential uses, including application to turf, there is also the potential for children at this age to be exposed via incidental oral exposures (e.g., hand to mouth, object to mouth and soil ingestion) from playing on treated lawns. The highest exposure for the incidental oral and dermal exposures would be 0.16 mg/kg/day (from hand-to-mouth behaviors for children) and 0.08 mg/kg/day, respectively. Combining exposures from the dietary and residential exposures for children would, therefore, result in an **aggregate exposure of 0.47 mg/kg/day**. These **calculations use a number of assumptions that have been extensively peer-reviewed....**"<sup>37</sup>

Thus, as OPP makes clear in its Revised cancer assessment, using OPP's standard exposure assessment methodologies which are based on peer-reviewed and validated exposure data and models, **a high-end estimate of combined exposure for children 1-2 years old is 0.47 mg/kg/day, or 47% of the cPAD.**

Yet, without any evidence or justification, EPA dismissed this combined exposure value by proposing that it is based on high end assumptions, and that "in actuality" these are too high – without providing any data or evidence to suggest how much of an over-estimate the combined exposure estimates may be.

"Incidental oral exposures from hand-to-mouth, object-to-mouth, and incidental soil ingestion are considered inter-related and, therefore, not combined. To calculate high end estimates of exposures, the following is assumed according to the 2012 SOP to be health-protective: 1) maximum label rates are applied to the turf, 2) exposures are assumed to occur every day to the residue values on the day of application (i.e., no dissipation), and 3) individuals engage in post-application activities for the maximum amount of time represented by data for children spending time outdoors and not specifically engaged in activities on turf, when in actuality children do not spend all of their outdoor time on turf."<sup>38</sup>

EPA's standard exposure assessment methods are developed through a lengthy rigorous public process involving opportunities for public comments, expert peer review, and public review of draft versions.<sup>39</sup> The final values in the Exposure Factors Handbook are developed using scientific studies, expert judgement, and public input. Further, it is intended to generate exposure estimates that are protective of all Americans, including those that spend more time playing on turf, eating dirt, and sucking on fingers. OPP cannot simply hand-wave these values away, simply because "children do not spend all of

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<sup>35</sup> EPA 2019 PID, p. 20-23

<sup>36</sup> Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential EPA's Office of Pesticide Programs. December 12, 2017. Appendix E

<sup>37</sup> Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential EPA's Office of Pesticide Programs. December 12, 2017. Appendix E and p. 136

<sup>38</sup> Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential EPA's Office of Pesticide Programs. December 12, 2017. Appendix E, p. 200

<sup>39</sup> <https://www.epa.gov/expobox/about-exposure-factors-handbook>

their outdoor time on turf” (see above). Does OPP know if its estimate reflected the 99.9<sup>th</sup> percentile children? The 99<sup>th</sup> percentile children? The 95<sup>th</sup> percentile children? Where is OPP’s data and support for its statement?

EPA’s cavalier approach runs counter to the FQPA’s dictate that EPA use at least a tenfold uncertainty factor to ensure infants and children are protected. Moreover, EPA must comply with the FQPA’s requirement that it ensure that infants and children’s cumulative and aggregate exposures shall be considered in determining whether any tolerance is fully protective of these vulnerable subpopulations. This, EPA has not done.

### **FQPA of 10X is legally required default factor**

As EPA is well aware, one of the Food Quality Protection Act’s (FQPA’s) key provisions is the requirement that EPA use an additional margin of safety to protect infants and children when establishing tolerances. The statute requires that, “an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.” 21 U.S.C. § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety “only if, on the basis of reliable data, such margin will be safe for infants and children.” *Id.*

There is extensive evidence that glyphosate and GBHs pose significant developmental hazards. Moreover, as is discussed in a later section of these comments, there also is evidence in the published scientific literature of the apparent endocrine disrupting effects of GBHs. Thus, it is clear that *at least* an additional tenfold uncertainty factor is required, based extensive evidence of their developmental hazards and critical data gaps detailed in these comments and in the referenced reports (incorporated herein).

Instead of protecting children, EPA eliminated the FQPA factor (reduced it to 1X), justifying this reduction in the margin of protection for children by finding that: the toxicological database is complete; early-life stage exposures are not more harmful than exposures during later life; there is no evidence of neurotoxicity; the POD used in risk assessment is below the dose associated with neurotoxicity in a 2-generational repro study; dietary and residential exposure analyses are conservative and do not underestimate exposure.<sup>40</sup>

The value from dietary exposure alone is 23% of the cPAD (of 1 mg/kg/day). If EPA had used the aggregate value, it would be 47% of the cPAD.<sup>41</sup> Both are considered below the Level of Concern (MOE for children is 260). However, if EPA had used an FQPA factor of only 10X, both would have exceeded the Level of Concern, triggering the need for regulatory action to reduce harmful exposures. See Table below:

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<sup>40</sup> Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential EPA’s Office of Pesticide Programs. December 12, 2017 . Appendix E. Docket ID EPA-HQ-OPP-2009-0361-0073

Glyphosate Draft Human Health Risk Assessment in Support of Registration Review, December 2017, See Section 7.0 aggregate risk assessment. Docket ID EPA-HQ-OPP-2009-0361-0068

<sup>41</sup> Glyphosate Draft Human Health Risk Assessment in Support of Registration Review, December 2017, See Section 7.0 aggregate risk assessment. Docket ID EPA-HQ-OPP-2009-0361-0068

FOR CHILDREN 1-2 yrs	FQPA 1X	FQPA 10X	Reference
Chronic (food and water) Dietary Exposure and Risk	23% of cPAD for children 1-2 yrs old	230% of cPAD; UNSAFE	EPA2017 HHRA, p. 21; EPA2019 PID, p. 20-21
Short-term aggregate risk (food, water, residential exposure)	38% of cPAD MOE =260	380% of cPAD MOE =26; UNSAFE	EPA2017 HHRA, p. 25; EPA2019 PID, p. 22
Short-term aggregate risk (above + dermal)	47% of cPAD MOE=213 <sup>42</sup>	470% of cPAD MOE=21; UNSAFE	EPA2017Revised Cancer Ass, Appendix E

**Glyphosate in food, water, and people**

Because glyphosate is systemic, being translocated into the plant, the herbicide and its metabolites are detected in foods, waterways and tap water, and in dust. This means that people can be exposed through ingesting of food and water, skin absorption and inhalation while bathing, and by direct contact with contaminated soil and dust.<sup>43</sup> The US FDA food testing FY2016 testing identified glyphosate in 63% of corn samples (173 total samples), and 67% of soybean samples (178 total samples);<sup>44</sup> all samples were below the government tolerance level, so were not considered legal violations.<sup>45</sup> Residues in plants and foods persist, even after cooking, baking, and processing. Residues have been found in infant formula, baby foods, oat cereals, and oatmeal snack bars. Friends of the Earth and partner groups reported in 2019 that glyphosate was detected in 100% of store-purchased oat cereals tested, with residues as high as 930 ppb.<sup>46</sup>

Glyphosate is getting into our bodies and has been doing so at increasing levels for decades—according to research in the prestigious medical journal JAMA (Journal of the American Medical Association). Researchers at the University of California measured levels of glyphosate in the urine of one hundred people. The subjects had been involved in a study since the 1970’s which allowed researchers to go back and look at historical and current levels of glyphosate in urine over decades. And, the trend is rising, as glyphosate crop uses rise across the country.

**IMPACTS TO MONARCH BUTTERFLIES**

EPA’s Proposed Interim Decision on glyphosate is completely unresponsive to the negative environmental impact that glyphosate is having on monarch butterflies.

<sup>42</sup> Aggregate MOE=100 /(combined exposure), where combined exposure is shown in EPA2017HHRA, Table 7.0, p. 25 (Dietary=0.23; Incident oral=0.156; Combined=0.387 mg/kg-day) with the addition of dermal exposure of 0.08 mg/kg-day.

<sup>43</sup> Zhang L, Rana I, Shaffer RM, Taioli E, Sheppard L, Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence, Mutation Research-Reviews in Mutation Research (2019), <https://doi.org/10.1016/j.mrrev.2019.02.001>

<sup>44</sup> Pesticide Residue Monitoring Program: Fiscal Year 2016 Pesticide Report. U.S. Food and Drug Administration. <https://www.fda.gov/media/117088/download>

<sup>45</sup> CFR Part 180 - Tolerances and exemptions for pesticide chemical residues on food. Subpart C - specific tolerances. §180.364 Glyphosate; tolerances for residues. <https://bit.ly/2Jj6sYL>

<sup>46</sup> Toxic Secret: Pesticides Uncovered In Store Brand Cereal, Beans, Produce. Friends of the Earth report. 2019 <https://foe.org/food-testing-results/>

## EPA ignores the scientific consensus that glyphosate is a leading cause of monarch decline

In the agency's Proposed Interim Decision on glyphosate, the EPA makes the following claims about having addressed concerns regarding the effect of glyphosate on monarch butterflies:

**"The EPA Response:** Monarch butterfly conservation is an important issue for the agency.

While herbicides like glyphosate have been implicated in the decline of the monarch butterfly population, it is not known to what extent pesticides in general may play a role. It is important to note that threats to the monarch butterfly population are multi-pronged and include loss of breeding habitat, loss of overwintering habitat in Mexico<sup>2</sup>, changes in weather patterns (including winter storms), disease, and other factors<sup>3</sup>."

<sup>2</sup> Vidal, O., Lopez-Garcia, J., and Rendon-Salinas, E. (2014), Trends in Deforestation and forest Degradation after a Decade of Monitoring in the Monarch Butterfly Biosphere Reserve in Mexico. *Conservation biology*, 28: 177-186.

<sup>3</sup> Agrawal, A. and Inamine, H. (2018), Mechanisms behind the monarch's decline. *Science*, 22: vol. 360, Issue 6395, pp. 1294-1296.

In making this statement, EPA attempts to shift the focus of monarch decline away from glyphosate use and towards other causes. For example, EPA suggests that other pesticides could be contributing to the monarch's decline. We agree that other pesticides could be contributing to the monarch's decline and EPA should also determine and address the impact of these other pesticides on the monarch butterfly. However, that does not release EPA from its obligation to analyze and address the impact of glyphosate on monarch butterflies.

EPA also points to other "multi-pronged" threats to monarch butterflies. While a variety of factors influence the population size of monarch butterflies, studies that have examined the relative contribution of these factors have all determined that the loss of agricultural milkweed habitat from the use of glyphosate is one of the leading causes of monarch decline.<sup>47</sup> There is broad consensus amongst monarch butterfly experts that the driving force behind the butterfly's decline is the loss of milkweed in the United States due to the widespread use of glyphosate.<sup>48</sup> While other factors affect the butterfly population— such as weather, climate, and deforestation in the Mexican overwintering sites— experts agree that the loss of milkweed is one of the largest contributing factors, if not the leading factor. A recent study examining the various threats to the monarch population concluded that, "[w]hile climatic factors, principally breeding season temperature, were important determinants of annual variation in abundance, our results indicated strong negative relationships between population size and habitat loss

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<sup>47</sup> D.T. Tyler Flockhart et al., *Unravelling the Annual Cycle in a Migratory Animal: Breeding-season Habitat Loss Drives Population Declines of Monarch Butterflies*, *J. Animal Ecology*, 2014, at 7-8, Thogmartin, W. E et al. 2017. *Monarch butterfly population decline in Norther America: identifying the threatening processes*. *Royal Society Open Sci* 4: 170760, Wilcox, A. E. et al. 2019. An evaluation of studies on the potential effects contributing to the decline of eastern migratory North American Monarch Butterflies (*Danaus plexippus*). *Frontiers in Ecology and Evolution* 7: 1-12.

<sup>48</sup> See Thogmartin, W. E et al. 2017. *Monarch butterfly population decline in Norther America: identifying the threatening processes*. *Royal Society Open Sci* 4: 170760 [hereafter Thogmartin et al. 2017a]; John M. Pleasants, *Monarch Butterflies and Agriculture, in Monarchs in a Changing World: Biology and Conservation of an Iconic Insect* (Karen Oberhauser et al. eds., forthcoming 2015), at 15-16 [hereinafter Pleasants]; D.T. Tyler Flockhart et al., *Unravelling the Annual Cycle in a Migratory Animal: Breeding-season Habitat Loss Drives Population Declines of Monarch Butterflies*, *J. Animal Ecology*, 2014, at 7-8 [hereinafter Flockhart et al.]; John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, *Insect Conservation & Diversity*, 2012, at 8 [hereinafter Pleasants & Oberhauser]; Lincoln P. Brower et al., *Decline of Monarch Butterflies Overwintering in Mexico: Is the Migratory Phenomenon at Risk?*, *Insect Conservation & Diversity*, 2011, at 1-4 [hereinafter Brower et al.].

variables, *principally glyphosate use*, but also weaker negative effects from the loss of overwinter forest and breeding season use of neonicotinoids” (emphasis added).<sup>49</sup> Another study concluded that “[r]ecent population declines stem from reduction in milkweed host plants in the United States that arise from increasing adoption of genetically modified crops and land-use change, not from climate change or degradation of forest habitats in Mexico.”<sup>50</sup> The authors further concluded that “[c]onserving monarch butterflies by addressing the negative impacts of changing land-use and the adoption of genetically modified, herbicide-resistant crops on host plant abundance is the highest conservation priority.”<sup>51</sup> Clearly, the scientific consensus is that the loss of milkweed due to the widespread use of glyphosate is responsible for the decline in the monarch population.

The loss of milkweed, particularly in the agricultural Midwest, has been well documented, and is the direct result of increased glyphosate use.<sup>52</sup> A survey of milkweed in corn and soybean fields in 1999 documented milkweed in at least fifty percent of fields. By 2009, milkweed was documented in only eight percent of the fields. Additionally, the overall area occupied by milkweed within the fields decreased by ninety percent.<sup>53</sup> Relying on this and other data, another study extrapolated the loss of milkweed in both agricultural and non-agricultural areas across the entire Midwest and found a sixty-four percent decline in milkweed from 1999 to 2012.<sup>54</sup> The authors of these studies attribute the decline in agricultural milkweed to the increased use of glyphosate following the introduction of glyphosate resistant crops which allow for the broadscale application of glyphosate throughout the growing season without damaging the crops.

Monarchs tend to lay more eggs in agricultural areas than in non-agricultural areas. Accordingly, the decline of milkweed in the largely agricultural Midwest has caused a greater-than-proportional reduction in successful monarch reproduction.<sup>55</sup> While there has been a sixty-four percent loss of milkweed in the Midwest, researchers estimate that this has corresponded with an eighty-eight percent decrease in monarch production.<sup>56</sup> During the same time period that researchers have measured the declines in milkweed and monarch production in the Midwest, there has also been a corresponding, statistically significant decline in the monarch overwintering population in Mexico.<sup>57</sup> The overwintering population has dropped from a high of approximately one billion butterflies in 1997 to a low of

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<sup>49</sup> Thogmartin, W. E. et al. 2017a.

<sup>50</sup> Flockhart et al. at 1; *see also* The Xerces Society for Invertebrate Conservation & U.S. Dep’t of Agric. Natural Resources Conservation Serv., *Pollinator Plants of the Central United States: Native Milkweeds* (2013), at 5 (“[D]ocumented declines in milkweed habitat and monarch breeding potential illustrate the urgent need to protect existing milkweed populations.”), *available at* [http://www.nrcs.usda.gov/Internet/FSE\\_PLANTMATERIALS/publications/mopmcpu11905.pdf](http://www.nrcs.usda.gov/Internet/FSE_PLANTMATERIALS/publications/mopmcpu11905.pdf).

<sup>51</sup> Flockhart et al. at 8.

<sup>52</sup> Pleasants, at 15-16.

<sup>53</sup> Robert G. Hartzler, *Reduction in Common Milkweed (Asclepias Syriaca) Occurrence in Iowa Cropland from 1999 to 2009*, 29 *Crop Protection* 1542, 1543 (2010).

<sup>54</sup> Pleasants at 1.

<sup>55</sup> Pleasants & Oberhauser; Pleasants at 1.

<sup>56</sup> Pleasants at 1.

<sup>57</sup> *See generally* Brower et al., at 1-4.

approximately 33.5 million butterflies.<sup>58</sup> Scientists have warned that the monarch migration is at risk of vanishing.<sup>59</sup>

As cited by EPA, a minority of researchers have argued that nectar availability during autumn migration is an important driving factor in determining overwintering population size thereby casting doubt on the importance of milkweed loss.<sup>60</sup> However, subsequent research determined that while autumn nectar availability impacts overwintering population size, so too does summer breeding habitat (i.e. milkweed availability) underscoring the importance of milkweed in driving population size.<sup>61</sup>

Although multiple factors contribute to determining the monarch butterfly population size, there is no credible disagreement that the loss of milkweed caused by the largescale use of glyphosate is a leading factor in the monarch's decline and therefore restricting its use is necessary in order for monarch butterflies to recover. "Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment." 40 C.F.R. § 155.40(a)(1). EPA's Proposed Interim Decision fails to satisfy this standard.

### **EPA's past and proposed actions do not meaningfully reduce glyphosate's risk to monarchs**

In the Proposed Interim Decision, EPA outlines various actions that it has taken to be responsive to the decline of monarch butterflies. For example, EPA states that:

A holistic approach is needed for monarch conservation and such an approach should consider herbicides in general as well as other factors that may play a role in the monarch decline. In addition, it is important to balance weed management needs with monarch conservation needs. To that end, the EPA published the Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly for public comment in 2015 (available in docket EPA-HQOPP-2015-0389 at [www.regulations.com](http://www.regulations.com)).

And that:

Overall, the EPA received good suggestions from stakeholders on how to manage risks to monarch butterflies. Suggestions from stakeholders include the following;

- i. broad stakeholder involvement, outreach, and partnering;
- ii. focusing on voluntary, incentive-based, and locally-led initiatives;
- iii. promotion and use of best management practices to reduce pesticide exposure;
- iv. promotion and use of integrated pest management;
- v. development of label language to protect the monarch butterfly;
- vi. supporting milkweed habitat in non-agricultural areas;
- vii. more communication, education, and outreach on the monarch butterfly;
- viii. continue to better understand monarch biology and needs; and

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<sup>58</sup> *Monarch Population Status*, Monarch Watch.org (Jan. 29, 2014, 12:10 PM), <http://monarchwatch.org/blog/2014/01/monarch-population-status-20/> (expressing monarch population in terms of hectares colonized; one colonized hectare contains approximately 50 million butterflies).

<sup>59</sup> See generally Brower et al. at 1-4; Semmens et al. 2016. Quasi-extinction risk and population targets for the Eastern migratory population of monarch butterflies (*Danaus plexippus*). *Nature Scientific Reports* 6:23265.

<sup>60</sup> Agrawal, A. and Inamine, H. (2018). Mechanisms behind the monarch's decline. *Science*, 22: vol. 360, Issue 6395, pp. 1294-1296.

<sup>61</sup> Saunders, S. P. et al. 2019. Multiscale seasonal factors drive the size of winter monarch colonies. *PNAS* 116: 8609-8614.

- ix. ensure that any actions taken are done in a manner that balances monarch conservation priorities with other priorities such as native and invasive weed control.

This list contains largely voluntary and education/outreach-based “suggestions” that are in no way sufficient for addressing the threats to monarch butterflies posed by glyphosate use as they do not require anyone to take actions, nor do they prohibit or restrict the use of glyphosate in any way.

The EPA also states that:

In general, the EPA has focused its monarch conservation efforts on activities that are within the purview of the Office of Pesticide Programs (OPP) and are possible to implement through OPP's registration review, registration, and stakeholder outreach activities. The EPA is focused on four main areas; label language; cooperative efforts between the EPA and other federal, state, and private partners/stakeholders; outreach and communication; promoting best management practices and integrated pest management; and science and risk assessment.

The agency then goes on to detail a number of “milestones” that it has achieved in the last several years. Again, most of these “monarch conservation activities” are entirely voluntary and do not guarantee that any actions have been taken by the states to implement them. Nor does the implementation of these voluntary actions guarantee a benefit to monarch butterflies sufficient to address the decline caused by glyphosate.

#### ***EPA's Cooperative Agreement Guidance is ineffective***

As an example of the agency's “monarch conservation efforts” the EPA points to its 2018-2021 FIFRA Cooperative Agreement Guidance for states which includes the development of managed pollinator protection plans. These plans are entirely voluntary and are primarily designed to help facilitate communication between stakeholders to reduce acute exposure of managed bees to pesticides by alerting beekeepers when farmers intend to treat their fields with pesticides such as neonics. A recent report by the Office of the Inspector General concluded that “EPA lacks a strategy to use survey data to assess MP3 results”.<sup>62</sup> Furthermore, the report found that the plans focus on acute, single exposure to managed pollinators (ie honey bees), but do not address chronic exposure to pesticides by native pollinators such as monarch butterflies.<sup>63</sup> Therefore, the Cooperative Agreement Guidance is ineffective for addressing the effect of glyphosate on monarch butterflies.

#### ***EPA's development of label language to protect the monarch butterfly is ineffective***

EPA points to label language that it has implemented. This language reads:

This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated area. Protect the forage and habitat of non-target organisms by minimizing spray drift. For further guidance and instructions on how to minimize spray drift, refer to the Spray Drift Management section of this label.

Label language on an herbicide that says that it is toxic to plants is in no way an effective or protective measure since herbicides are by definition designed to be toxic to plants. Furthermore, this text suggests that the only threat to non-target organisms falls outside of the treated area (i.e. off-field). However, the decline in monarch butterflies has largely been a result of the loss of milkweed within

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<sup>62</sup> [https://www.epa.gov/sites/production/files/2019-08/documents/\\_epaog\\_20190815-19-p-0275.pdf](https://www.epa.gov/sites/production/files/2019-08/documents/_epaog_20190815-19-p-0275.pdf)

<sup>63</sup> *Id.*

agricultural fields.<sup>64</sup> Although there has been a pronounced loss of both agricultural and non-agricultural habitat for monarchs since the adoption of glyphosate-resistant crops, agricultural milkweed has disappeared at a faster rate and its loss is particularly detrimental to monarchs.<sup>65</sup> As mentioned above, monarchs tend to lay more eggs in agricultural fields than in non-agricultural areas. Accordingly, the decline of milkweed in the largely agricultural Midwest has caused a greater-than-proportional reduction in successful monarch reproduction.<sup>66</sup> Label language that only warns farmers of threats to pollinators *outside* of their treated field is not responsive to the cause of the decline of monarchs.

***EPA's promotion of best management practices to reduce pesticide exposure and promote integrated pest management is ineffective***

Similarly, the webinars that EPA has held to educate stakeholders on ways to reduce pesticide spray drift are also not responsive to the decline of monarch butterflies. While education can provide stakeholders with information, any action that they choose to take is entirely voluntary. Furthermore, as discussed above, reducing spray drift – even if effective – only addresses potential loss of milkweed outside the agricultural field rather than within the field.

Integrated Pest Management could be used effectively to reduce or eliminate the use of glyphosate and other pesticides. For example, rather than prophylactically spraying the entire field with glyphosate, as is the practice with glyphosate resistant crops, IPM would provide a variety of options (such as mechanical, physical or chemical control) in a restricted and targeted manner if and when a problematic weed was detected (not before). Other examples of IPM include the use of cover crops and diversified crop rotations which break up weed cycles without the use of herbicides.

However, without a specific mandate for the use of IPM, the adoption of IPM has been virtually non-existent among corn and soybean farmers since the introduction of glyphosate-resistant crops.<sup>67</sup> In fact, the most common use of glyphosate (which is in connection with glyphosate tolerant crops) is entirely antithetical to the principals of IPM which call for the selective use of pesticides and the use of a more diverse range of pest control tactics. According to EPA, “IPM programs take advantage of all appropriate pest management strategies, including the *judicious use of pesticides*. *Preventive pesticide application is limited* because the risk of pesticide exposure may outweigh the benefits of control, especially when non-chemical methods provide the same results” (emphasis added).<sup>68</sup> Instead, the use of glyphosate in connection with glyphosate tolerant crops has led to pesticide intensive agricultural practices dubbed by

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<sup>64</sup> John M. Pleasants, *Monarch Butterflies and Agriculture*, in *Monarchs in a Changing World: Biology and Conservation of an Iconic Insect* (Karen Oberhauser et al. eds., forthcoming 2015), at 15-16, John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation & Diversity, 2012, at 8.

<sup>65</sup> John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation & Diversity, 2012.

<sup>66</sup> K.S. Oberhauser et al., *Temporal and Spatial Overlap Between Monarch Larvae and Corn Pollen*, 98 Proc. Nat'l Acad. Sci. U.S. 11913, 11917 (2001), John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation & Diversity, 2012.

<sup>67</sup> Hurley, T.M. 2016. “Shock and Awe Pest Management: Time for Change.” Choices. Quarter 4. Available online: <http://www.choicesmagazine.org/choices-magazine/theme-articles/herbicide/shock-and-awe-pest-management-time-for-change>, Hurley and Huichun. 2019. Softening Shock and Awe Pest Management in Corn and Soybean Production with IPM Principles. Journal of Integrated Pest Management 10: 1-8.

<sup>68</sup> <https://www.epa.gov/managing-pests-schools/introduction-integrated-pest-management>

some researchers as “Shock and Awe Pest Management” where pesticides (such as glyphosate) are used liberally and prophylactically rather than in response to an actual pest problem.<sup>69</sup>

Therefore, EPA’s webinars to educate stakeholders on ways to reduce pesticide spray drift and to use integrated pest management principles are wholly ineffective.

***EPA’s drift mitigation measures are ineffective***

EPA claims that they imposed drift mitigation measures through this Proposed Interim Decision. Specifically, the agency conducted a spray drift analysis for both aerial and ground application of glyphosate for milkweed and for cucumber, the most sensitive plant species tested. The results of the spray drift analysis suggest that a buffer distance of 118 ft – 620 ft is needed for aerial application to protect milkweed outside of the field. And that a buffer distance of 33-157 ft would be needed for ground application. Despite these findings, the EPA’s drift mitigation measures only make specifications to boom height, application height and droplet size, but they do not call for ANY buffer distance.

These proposed mitigation measures are inadequate in two ways. They do not address the risk to milkweed outside of the field, because they do not call for a buffer at all despite the agency’s own analysis showing the need for buffers in the range of 33 to 620 feet to be protective of milkweed outside the field. The drift mitigation is also inadequate because it is only concerned with mitigating harm to milkweed outside the field even though monarch decline has occurred because of loss of milkweed within agricultural fields.<sup>70</sup>

**EPA has failed to analyze or implement viable alternatives to the use of glyphosate**

Viable alternatives exist for addressing the impact of glyphosate on monarch butterflies and EPA has failed to analyze or implement any of them.

***EPA failed to address the impact of glyphosate outside of agricultural fields***

EPA is proposing to impose very minimal spray drift restrictions on glyphosate by making adjustments to boom height, application height and droplet size. However, EPA has entirely failed to implement any buffer restrictions for in field use of glyphosate despite its own analysis demonstrating a need for buffers of up to 157-620 feet to be protective of plants outside of agricultural fields. EPA does not provide any meaningful explanation for why it did not impose buffer restrictions for glyphosate. In order to address impacts to milkweed outside of agricultural fields, EPA should institute a significant buffer to prevent damage outside the field.

***EPA failed to address the impact of glyphosate within agricultural fields***

As discussed above, it is not sufficient to only address the impact of glyphosate to areas outside of agricultural fields since the cause of the decline of the monarch butterfly is primarily due to glyphosate

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<sup>69</sup> *Id.*

<sup>70</sup> John M. Pleasants, *Monarch Butterflies and Agriculture*, in *Monarchs in a Changing World: Biology and Conservation of an Iconic Insect* (Karen Oberhauser et al. eds., forthcoming 2015), at 15-16, John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, *Insect Conservation & Diversity*, 2012, at 8.

use within agricultural fields. A recent study determined that agricultural land, particularly in the Midwest, is critical to the survival of monarch butterflies and therefore at least 10% of agricultural land will be needed to support milkweed in order to recover a sustainable population of monarch butterflies.<sup>71</sup> The authors conclude that it may be possible to cultivate milkweed within agricultural land “if issues with pesticides can be overcome.”<sup>72</sup>

The main obstacle to returning milkweed to agricultural fields is the persistent use of glyphosate in connection with glyphosate resistant crops. The reason that glyphosate (rather than any other herbicide) has contributed so significantly to the decline of the monarchs is because of its use in connection with crops that have been genetically engineered to resist glyphosate. After the introduction of these crops, the use of glyphosate increased dramatically. For example, between 1989 and 1991, before the genetically engineered crops were developed, 18.7 million pounds of glyphosate were used on between thirteen and twenty million acres annually; between 2008 and 2009, 182 million pounds were used on over 261 million acres— an approximate tenfold increase.<sup>73</sup>

Moving away from glyphosate-resistant cropping systems and placing restrictions on the use of glyphosate would allow milkweed to return to agricultural fields while still providing flexibility for farmers to address other types of weeds. As mentioned above, true Integrated Pest Management provides a suite of options for addressing problem pests but is applied in strategic and targeted ways rather than the broadscale, prophylactic way that glyphosate is currently used. Such options include rotating crops, planting cover crops, mechanical or targeted chemical removal of problem weeds. For example, studies have shown that diversifying crop rotations can help reduce the amount of herbicide use by 97%.<sup>74</sup> Even according to EPA, one of the key principles of IPM is that it “Uses pesticides only as needed” (emphasis added).<sup>75</sup> The use of glyphosate in connection with glyphosate resistant crops uses pesticides regardless of whether there is a problem pest present or not which is clearly inconsistent with the principles of IPM.

Additionally, promising research out of Idaho State University demonstrates that planting strips of native prairie (which can include milkweed) within agricultural fields provides significant benefits to farmers including reducing soil erosion and enhancing soil quality in addition to providing habitat for pollinators.<sup>76</sup> These prairie strips have been successful even when implemented within conventional agricultural fields. Such prairie strips provide a mechanism for returning milkweed to agricultural fields. In fact, prairie strips are implemented by converting 10% of an agricultural field into native prairie which

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<sup>71</sup> Thogmartin, W. E. et al. 2017. Restoring monarch butterfly habitat in the Midwestern US: all hands on deck. *Environmental Research Letters* 12:074005. [hereafter Thogmartin et al. 2017b]

<sup>72</sup> *Id.*

<sup>73</sup> Comments of the Natural Resources Defense Council on Dow Agrosiences’ Application to Register Enlist Duo Herbicide Containing the Choline Salt of 2,4-D and Glyphosate (June 30, 2014), at 7-9.

<sup>74</sup> Matt Liebman and Lisa A. Schulte, “Enhancing Agroecosystem Performance and Resilience through Increased Diversification of Landscapes and Cropping Systems,” *Elementa: Science of the Anthropocene* 3 (February 12, 2015): 000041, doi:10.12952/journal.elementa.000041. Adam S. Davis et al., “Increasing Cropping System Diversity Balances Productivity, Profitability and Environmental Health,” *PLoS ONE* 7, no. 10 (October 10, 2012): e47149, doi:10.1371/journal.pone.0047149.

<sup>75</sup> <https://www.epa.gov/managing-pests-schools/introduction-integrated-pest-management>

<sup>76</sup> See <http://www.nrem.iastate.edu/research/STRIPs/>

is consistent with the amount of agricultural land that scientists have estimated is needed to support a sustainable population of monarch butterflies.<sup>77</sup>

A variety of options exist for mitigating the impact of glyphosate on monarch butterflies within agricultural fields such as imposing restrictions to glyphosate use particularly in connection with glyphosate resistant crops, mandating the use of effective integrated pest management practices such as crop rotations and cover crops, and converting 10% of agricultural fields to native prairie strips. EPA failed to consider any of these feasible alternatives for reducing the impact of glyphosate on milkweed within agricultural fields.

### ***EPA failed to require the use of Integrated Pest Management***

EPA should require Integrated Pest Management to reduce reliance on pesticides and prevent the evolution of herbicide-resistant weeds. True IPM is inconsistent with glyphosate-resistant cropping systems. Integrated pest management focuses on weed control, rather than weed eradication, in an effort to control weeds using the least environmentally destructive means possible. Methods to decrease weed abundance include rotating crops, cleaning equipment to remove plant residue, mechanical weed control, and using cover crops during the off-season. By preventing weed growth, integrated pest management can dramatically reduce herbicide use and herbicide resistance. EPA should mandate some or all of these methods for farmers using glyphosate to reduce the volume of glyphosate needed.

### **Glyphosate presents an unreasonable risk of harm to monarch butterflies**

Registration review determines whether a registered pesticide still satisfies FIFRA's registration standard. 7 U.S.C. § 136a(g); 40 C.F.R. § 155.40(a). FIFRA prohibits EPA from approving a pesticide unless, among other things, "when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). The statute defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). Consequently, during registration review, EPA must balance a pesticides risks against its benefits to determine if the risks are unreasonable. *See* 40 C.F.R. §§ 155.40(a), 155.57. The Proposed Interim Decision ignores important aspects of glyphosate's harms to butterflies, does not address the availability of less harmful alternatives, and overstates its benefits.

### ***Even taking into account EPA's proposed mitigation measures, glyphosate presents an unreasonable risk to monarchs***

Due to the use of glyphosate, the monarch butterfly population is threatened with extinction. The migrating monarch population is already so diminished that its prospects for recovery are fading.<sup>78</sup> Continued milkweed loss renders the population susceptible to further decline, compromising its ability to withstand additional stressors such as severe weather, freezing temperatures, disease, predation, and deforestation.. In 2002, a single storm killed more than 450 million monarchs, which constituted

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<sup>77</sup> Thogmartin et al. 2017b

<sup>78</sup> Brower et al. at 1-4; Semmens et al. 2016

approximately 75 percent of the overwintering population—and exceeded, by over three times, the 150 million monarchs overwintering in Mexico during the 2015-2016 season.<sup>79</sup> Owing to its current size, the monarch population is susceptible to complete eradication by comparable storms.

Continued suppression of milkweed across the butterflies' breeding grounds perpetuates the risk of monarch population collapse, and additional milkweed destruction exacerbates that risk. The population is so precariously small that experts—including those at the US Geological Survey—have warned that the monarch migration may be coming to an end.<sup>80</sup> In 2016, a group of academic researchers and scientists from federal and state agencies jointly published a study finding that migrating eastern monarchs face a “high probability of quasi-extinction [that is, population collapse] over the next two decades.”<sup>81</sup> “Given the population’s present low numbers,” the study concluded, “poor reproductive success by monarchs in future breeding seasons due to weather conditions and reduced breeding habitat, followed by catastrophic mortality while over-wintering in Mexico, could bring the monarch migration to the brink of extinction.”

***EPA has failed to evaluate the true cost of glyphosate and has overstated its benefits***

FIFRA requires EPA to balance a pesticide’s benefits against its harms to determine if the risks it presents are unreasonable. 7 U.S.C. §§ 136(bb), 136a(c)(5)(D). The Proposed Interim Decision fails to meaningfully engage this statutorily mandated risk-benefit balancing task. The harms of glyphosate use outweigh the benefits. In addition to threatening the very existence of monarch butterflies, the use of glyphosate presents a full suite of negative environmental and human health consequences including increasing weed resistance, diminished effectiveness which leads to increased use of both glyphosate and additional herbicides, diminished water quality and wildlife abundance and both acute and long-term human exposure. EPA has failed to adequately address these costs of glyphosate use.

Due to the ubiquitous use of glyphosate, glyphosate resistant weeds have developed into a major threat to agriculture. While the EPA mentions the issue of weed resistance in its PID, the agency makes no attempt to analyze or evaluate the role of glyphosate specifically in the proliferation of weed resistance nor does it examine the cost of weed resistance simply stating that “Weed resistance commonly occurs but despite resistance problems, glyphosate remains an important weed management tool”.<sup>82</sup> The USDA’s own research has shown that “an overreliance on glyphosate and a reduction in the diversity of weed management practices adopted by crop producers have contributed to the evolution of glyphosate resistance in 14 weed species and biotypes in the United States.”<sup>83</sup> One study estimated the cost that glyphosate resistant weeds have caused in damages to water quality and climate effects between 1999-2006. The authors conservatively estimate the cost at \$450 million dollars.<sup>84</sup> The EPA failed to account for any costs associated with glyphosate use due to glyphosate resistant weeds.

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<sup>79</sup> Brower et al. 2004. Catastrophic winter storm mortality of monarch butterflies in Mexico during January 2002. *The Monarch Butterfly: Biology and Conservation*. 151-166.

<sup>80</sup> Semmens et al. 2016

<sup>81</sup> *Id.*

<sup>82</sup> EPA. 2019. Glyphosate Proposed Interim Registration Review Decision. Docket Number EPA-HQ\_OPP-2009-0361.

<sup>83</sup> USDA 2014 Genetically engineered crops in the United States. Economic Research Service Report 162.

<sup>84</sup> Braeden Van Deynze, Scott Sinton and David Hennessy. 2018. Are Glyphosate-Resistant Weeds a Threat to Conservation Agriculture? Evidence from Tillage Practices in Soybean. Selected paper prepared for presentation at the Agricultural and Applied Economics Association Annual Meeting, Washington DC. August 5-7, 2018.

Seed companies have responded to glyphosate resistant weeds by developing crops that are resistant to both glyphosate and a second herbicide like 2,4-D or Dicamba. This unsustainable solution, which is a result of the overuse of glyphosate, further amplifies the environmental consequences of herbicide use. EPA has failed to evaluate the economic and ecological cost of transitioning towards the use of multiple herbicides as a result of glyphosate becoming less effective on resistant weeds.

Furthermore, EPA failed to analyze the costs and benefits of alternatives to glyphosate use such as organic farming, integrated pest management, diverse crop rotations and cover crops. For example, one study found that even without accounting for the environmental costs of conventional farming or the ecosystem services of organic farming that “when actual premiums were applied, organic agriculture was significantly more profitable... and had higher benefit/cost ratios...than conventional agriculture”.<sup>85</sup> Other studies found that using diverse cropping rotations reduced the amount of herbicide needed to control weeds by 88-97%.<sup>86</sup> EPA failed to analyze any economic or ecological cost to using glyphosate and similarly failed to analyze any economic or ecological benefit to not using glyphosate. In doing so, the agency has ignored the environmental costs and mistakenly overinflated the benefits of glyphosate use.

## LOSING IN THE COURTS

With two multi-million-dollar verdicts in the US courts holding Monsanto liable for NHL cancers caused by years of exposure to GBH products, and another 13,400 claims to be decided, it is no wonder that Bayer CEO lost a shareholder confidence vote last month. Bayer AG's stock values have already dropped by two-fifths of their value (about \$34 billion US) prior to acquiring Monsanto on June 7, 2018 (for \$63 billion US). Bayer's Chief Executive is still mischaracterizing the US lawsuits and liabilities as based on nothing more than an, “outlier assessment of the potential risk by a subordinate organization”, meaning IARC.<sup>87</sup> Nothing could be farther from the truth.

## CONCLUSION

OPP's continued denial of the cancer evidence is unexplainable by science. This is not an issue upon which reasonable experts may disagree. In fact, reasonable experts agree – people exposed to GBH products are at an increased risk of developing NHL cancer. Non-regulatory US health agencies agree, non-industry academic experts agree, juries and court judges agree, and investors and shareholders agree.

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<sup>85</sup> Crowder, D. W. and J. P. Reganold. Financial competitiveness of organic agriculture on a global scale. Proceedings of the National Academy of Sciences 112: 7611-7616.

<sup>86</sup> Davis et al. 2012. Increasing cropping system diversity balances productivity, profitability and environmental health. PLOS ONE 7: e47149 (8 pages). Matt Liebman and Lisa A. Schulte, “Enhancing Agroecosystem Performance and Resilience through Increased Diversification of Landscapes and Cropping Systems,” *Elementa: Science of the Anthropocene* 3 (February 12, 2015): 000041, doi:10.12952/journal.elementa.000041

<sup>87</sup> Reuters, April 11, 2019. <https://www.reuters.com/article/us-bayer-ceo/ceo-sees-bayer-massively-affected-by-herbicide-litigation-idUSKCN1RN0WS>

EPA should impose at least a tenfold uncertainty factor as required by the FQPA. The agency also should not deviate from its own risk assessment methodologies by hand waiving away the excessive exposure of young children to GBHs. We further urge EPA to consider the extensive evidence of carcinogenicity, and to regulate it as such under the FQPA. At an absolute minimum, and in the alternative, EPA should immediately grant the pending petition to prohibit preharvest uses of GBHs.

EPA has ignored critical science documenting the role of glyphosate in monarch's decline. Building on that flawed foundation, the minor mitigation measures that EPA outlines for glyphosate use in its interim decision are wholly unresponsive to the drastic decline in monarch butterflies that glyphosate has caused and continues to cause. EPA has failed to conduct a reasonable analysis of the information available to it regarding glyphosate's harms to monarchs and available mechanisms for reducing that harm. A full accounting of glyphosate's risks would reveal them to be unreasonable.

As described above, the mitigation measures proposed by EPA have failed and will continue to fail to address glyphosate overuse as a primary driver of monarch decline. The reregistration of glyphosate presents an unreasonable risk to the environment because it threatens the extinction of monarchs (along with a host of other environmental and human health harms) and because this threat is entirely avoidable.

EPA, USDA and other Agencies must work together to promote effective and affordable non-chemical weed control measures, such as integrated pest management techniques like diverse crop rotations and cover crops, and native prairie strips, would increase agricultural milkweed habitat and help spur monarch recovery.

Finalizing the Proposed Interim Decision would violate FIFRA.

Thank you for the opportunity to submit comments.

Respectfully,



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