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Ms. Dana Friedman
Pesticide Re-Evaluation Division (7508P)
Environmental Protection Agency, Office of Pesticide Programs
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001

Re: Comments on the Human and Ecological Risk of Glyphosate and Other Chemical in Response to Federal Register Vol. 83, No. 39, 1846-1848

Dear Ms. Friedman,

Please accept these comments to the U.S. Environmental Protection Agency (U.S. EPA) in response to the Federal Register (FR 2018) entitled: *Registration Review; Draft Human Health and/or Ecological Risk Assessments for Several Pesticides; Notice of Availability*. The comments have been created for the Living Rivers Council, a Napa, California based non-profit group that has as its mission "to protect, restore, defend and preserve watersheds in natural harmony with people and wildlife." I am a consulting fisheries biologist and watershed scientist with extensive experience in assessing ecological impacts of pesticides and herbicides (see below). Although the FR (2018) notice includes several chemicals besides glyphosate, LRC is most concerned with the latter chemical and these comments, therefore, I focus on that substance exclusively in the discussion below.

Executive Summery

There are several critical flaws in the U.S. EPA approach to studying and regulating glyphosate. While the U.S. EPA studies the health and ecological effects of pure glyphosate, numerous studies show that binders can increase harmful effects and lethality. These substances can act with glyphosate but may also be toxic when acting alone. The U.S. EPA does not deal with the fact that the glyphosate degradant AMPA has a long life in soil and poses equal or greater biological risk. Risk to individual organisms, ecosystems and humans is under-estimated due to this study design flaw. Impacts to amphibians are ignored by the U.S. EPA and the glyphosate product Roundup is known to be deadly to them. Ecological impacts include the near disappearance of the Monarch butterfly because glyphosate killed off its host plant. Glyphosate is also very soluble in water and may persist and directly impact downstream organisms if sediment is not available in the water column to bind it. Glyphosate is now widespread in surface waters and is found even in rainfall, and yet the U.S. EPA says that most is bound in soils.

U.S. EPA human health risk assessment of glyphosate finds studies related to carcinogenicity are inconclusive, but there is an increasing body of evidence that glyphosate and binders are carcinogenic and hormone disruptors. Herbicide binders and the glyphosate degradant AMPA can break down cell walls and increase human health effects.

My Qualifications

I have acquired considerable expertise pertaining to pesticides and herbicides working for clients over the last 20 years. I am acquainted with the literature due to environmental protection work for Indian Tribes (Resighini Rancheria 2010, QVIR 2016) that served the purpose of protecting their water supplies and Tribal Trust resources. I also assessed potential problems from application of herbicides related to the proposed Bohemian Grove timber harvest plan (1-06 NTMP-011SON) and potential cumulative effects of pesticides and herbicides in the lower Russian River (Higgins 2007). Other timber harvest related reviews having to do with applications of pesticides and herbicides include the Kidd Creek Non-Industrial Timber Management Plan (1-15 NTMP-007 SON) (Higgins 2017a) and the Fox Meadows THP (THP 1-17-017 SON), which are both also in the Russian River watershed.

I became extremely well versed in the use of pesticides and herbicides and their ecological impact while working on the Salinas River for the Monterey Coastkeeper and the Stanford Environmental Law Center (Higgins 2009). My knowledge expanded greatly in service to the two latter clients, but also Earth Rise, when I created the *Conditions Report on the San Joaquin, Merced, Tuolumne and Stanislaus Rivers and Effects of East San Joaquin Pollution on Downstream Receiving Waters Including the San Francisco Bay Delta Ecosystem* (Higgins 2017b). I found that the synergistic effects of pesticides and herbicides were driving Pacific salmon species extinct in the San Joaquin River and causing the ecological collapse of the San Francisco Bay-Delta ecosystem.

Glyphosate Overview

This is an organophosphorus broad-spectrum herbicide used to kill weeds, especially annual broadleaf weeds and grasses that compete with crops. Marketed as Roundup since 1974, more than hundreds of millions of pounds are used on crops including corn, soybeans, wheat, cotton, rice, alfalfa, and pastures (Saunders and Pezeshki 2015). Use of the product increased as glyphosate resistant crops were developed. Essentially glyphosate kills all broadleaf plants it comes in contact with that aren't bred to be resistant to it. Toxicity may be increased depending on other contents added as binders (Saunders and Pezeshki 2015). It adheres strongly to clay soils, but can run off and contaminate surface waters, if is not filtered to through soil or riparian vegetation (Saunders et al. 2007). If streams are fairly free of suspended sediment, glyphosate can stay suspended for up to two weeks, but it rarely leaches to groundwater.

Glyphosate Degradant Aminomethylphosphonic Acid (AMPA)

The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). Studies show that is degrades more slowly than glyphosate because it has an even stronger adherence to soil particles and has less of a tendency to be broken down by micro-organisms. Horner (1990) found that the average half-life for the dissipation of glyphosate was 100 days and 118 days for AMPA. In a Midwestern study (Battaglin et al. 2005):

> "Glyphosate was detected at or above 0.1 µg/l in 35 percent of pre-emergence, 40 percent of post-emergence, and 31 percent of harvest season samples, with a maximum concentration of 8.7 µg/l. AMPA was detected at or above 0.1 µg/l in 53 percent of pre-emergence, 83 percent of post-emergence, and 73 percent of harvest season samples, with a maximum concentration of 3.6 µg/l."

Saunders and Pezeshki (2015) point out that AMPA "is phytotoxic in its own right, negatively affecting plant physiology." Scribner et al. (2003) monitored widely in Midwestern states and stated that "Results show that AMPA was detected more frequently and occurred at similar or higher concentrations than the parent compound glyphosate." Benachour et al. (2007) noted that the substance may also have some potential impact on human health: "AMPA and Polyethoxylated tallow amine (POEA) act separately and synergistically to damage cell membranes."

Therefore, the U.S. EPA (2017a, 2017b, 2017c) studies of the effects of glyphosate-based herbicides under-estimate its impacts because they do not fully consider the effects of its main break-down product that is even more persistent in the environment and sometimes more toxic. U.S. EPA (2017a) carried results of a study showing potential human health effects of AMPA and binder POEA stating that "AMPA was more toxic to human cells than glyphosate" (p 100 of 204). Yet AMPA goes unmonitored in the environment or within humans that are widely exposed to Roundup. That exposure is growing through our food supply chain due to the Roundup ready crops that now dominate the American market.

Binders and Adjuvants Not Inert – In Fact More Toxic Than Glyphosate

Substances are added to glyphosate to help the chemical penetrate cell walls and for more uniform application and these are called binders, surfactants or adjuvants. Numerous studies have concluded that binders may significantly change the toxicity of the product applied to well beyond effects caused by glyphosate alone (Schuett 1998, Relyea 2005, Gasnier et al. 2009, Vera et al. 2012, Saunders and Pezeshki 2015, Mesegne et al. 2015, Defarge et al. 2018). Defarge et al. (2018) noted that the surfactant POEA is a major component of Roundup and that it is itself a far greater toxicant than glyphosate. Their study exposed plants and human cells to component formulations of glyphosate-based herbicides and found some surprising and alarming things:

> "Glyphosate was only slightly toxic on plants at the recommended dilutions in agriculture, in contrast with the general belief. In the short term, the strong herbicidal and toxic properties of its formulations were exerted by the POEA formulant family alone."

Relyea (2005) found much higher toxicity to frogs and tadpoles from Roundup with POEA than from pure glyphosate in a controlled experiment. He concluded “high mortality associated with commercial forms of Roundup is actually due to the POEA surfactant and not to glyphosate itself.”

Defarge at al. (2018) point out the duplicity involved in analyzing impacts of glyphosate, often not in combination with binders or formulants:

> “In the short term, the strong herbicidal and toxic properties of its formulations were exerted by the POEA formulant family alone. The toxic effects and endocrine disrupting properties of the formulations were mostly due to the formulants and not to glyphosate.”

Gasnier et al. (2009) noted problems with POEA in terms of human health:

> “The adjuvants in Roundup formulations are not inert. Moreover, the proprietary mixtures available on the market could cause cell damage and even death around residual levels to be expected, especially in food and feed derived from Roundup formulation-treated crops.”

Mesegne et al. (2013) had corollary findings:

> “Here we demonstrate that all formulations are more toxic than glyphosate, and we separated experimentally three groups of formulations differentially toxic according to their concentrations in ethoxylated adjuvants. Among them, POE-15 clearly appears to be the most toxic principle against human cells…..Altogether, these results challenge the establishment of guidance values such as the acceptable daily intake of glyphosate, when these are mostly based on a long term in vivo test of glyphosate alone. Since pesticides are always used with adjuvants that could change their toxicity, the necessity to assess their whole formulations as mixtures becomes obvious.”

Cox and Surgan (2006) called for mandated monitoring of binders to comply with federal law:

> “Evaluations of pesticides under the National Environmental Policy Act, the Endangered Species Act, and similar statutes should include impact assessment of formulations. Environmental monitoring for pesticides should include inert ingredients. To enable independent research and risk assessment, inert ingredients should be identified on product labels.”

U.S. EPA (2017a) found that oral and inter-tracheal administration of glyphosate to rats caused only mild lung hemorrhages and epithelial damage, but rats died immediately or after several days when given POEA (p 96 of 204). Therefore, U.S. EPA knows that POEA is not inert and instead is highly toxic and yet it fails to monitor this substance.

Mesegne et al. (2015) summed up the problems of adjuvants and current regulation loop holes:

> “Glyphosate-based herbicides (GlyBH), including Roundup, are the most widely used pesticides worldwide. Their uses have increased exponentially since their introduction on the market. Residue levels in food or water, as well as human exposures, are escalating. We have reviewed the toxic effects of GlyBH measured below regulatory limits by evaluating the published literature and regulatory reports. We reveal a coherent body of evidence indicating that GlyBH could be toxic below the regulatory lowest observed adverse effect level for chronic toxic effects. It includes teratogenic, tumorigenic and hepatorenal effects. They could be explained by endocrine disruption and oxidative stress, causing metabolic alterations, depending on dose and exposure time.
>
> Some effects were detected in the range of the recommended acceptable daily intake. Toxic effects of commercial formulations can also be explained by GlyBH adjuvants, which have their own toxicity, but also enhance glyphosate toxicity. These challenge the assumption of safety of GlyBH at the levels at which they contaminate food and the environment, albeit these levels may fall below regulatory thresholds. Neuro-developmental, reproductive, and transgenerational effects of GlyBH must be revisited, since a growing body of knowledge suggests the predominance of endocrine disrupting mechanisms caused by environmentally relevant levels of exposure.”

Thus, the entire U.S. EPA analysis of impacts of glyphosate and its major derivative Roundup is flawed because the supposed “inert” binder POEA is the actual toxicant. Since POEA is not studied separately, we have no idea of its prevalence in the environment or in humans. Therefore, the U.S. EPA should deny further continued use of Roundup and similar glyphosate-based herbicides, following the precautionary principal, and require the removal of POEA from formulations.

Heavy Metals in Glyphosate-Based Herbicides

Defarge et al. (2018) found major problems with heavy metal pollution in glyphosate-based herbicide formulations:

> “We measured in the formulations other contaminants such as, among others, the heavy metals arsenic (As), cobalt (Co), chromium (Cr), nickel (Ni) and lead (Pb), which are known to be toxic and endocrine disruptors. Eleven formulations were assessed, as well as 11 other pesticide formulations as comparators. Formulations from both groups were comparably and heavily contaminated (Fig. 5) with the heavy metal As, present in almost all samples. In total, all except 3 formulations had 5–53 times the permitted level of As in water in European Union or USA; all except 1 had Cr above (up to 40 times) the permitted level; all except 1 contained Ni, with 19 samples being above the permitted level (up to 62 times); 6 contained up to 11 times the permitted level of Pb.”

This is extremely alarming and shows major negligence of the U.S. EPA in regulating Roundup and other glyphosate-based herbicides, if the findings of Defarge et al. (2018) are representative. If they are, the consequences for human and environmental health are far-reaching. The permitting of Roundup and other similar products should be withdrawn from the market, at least until heavy metal pollution issues are resolved.

Dispersal – Problems in the Water, the Soil and the Air

The U.S. EPA ecological assessment of glyphosate in the environment follows a simplistic logic that the chemical adheres to sediment and will not likely runoff, and that impacts and risk is mostly at the site of application. In fact, that is not the case and dispersal of glyphosate-based herbicides offsite is common in surface water, on the wind, and even in the rain (Scribner et al. 2003). Problems in the soil proximate to applications of glyphosate herbicides are underestimated by U.S. EPA, as the longevity of in the soil may also come with residual toxicity to non-target plant species and organisms essential to sustainable agriculture like earth worms.

Coupe et al. (2011) studied Midwestern streams and found glyphosate to be ubiquitous in surface waters:

> "Glyphosate use in a watershed results in some occurrence in surface water; however, the watersheds most at risk for the offsite transport of glyphosate are those with high application rates, rainfall that results in overland runoff, and a flow route that does not include transport through the soil."

Saunders and Pezeshki (2015) had the following findings: "(1) glyphosate often runs off of fields where it is applied; (2) glyphosate can be translocated by plant roots; and (3) glyphosate can affect plant functioning in non-target plants." Roots of plants killed is another pathway into the soil for glyphosate, AMPA and POEA. Glyphosate may and AMPA may remain for up to 196 days in clay soils with unknown biological impact as noted by Scribner et al. (2003).

Scribner et al. (2003) not only found surface water runoff with glyphosate-based herbicides, but also found them in isolated ponds where aerosol drift carried them. Furthermore, Scribner et al. (2003) actually measured glyphosate and AMPA in rainfall in Mid-western states. A U.S. Geological Survey (USGS 2008) found substantial amounts of glyphosate in runoff in a Clackamas River tributary after forest herbicide application.

The U.S. EPA needs to acknowledge the potential for some pesticides and herbicides to have impacts many miles from their application location (Cordell and Baker 1998). Although the incidence of contamination is not involving glyphosate, Davidson and Knapp (2007) found that pesticides applied on the southern Central Valley floor are killing mountain yellow-legged frogs inside Wilderness Areas along the crest of the Sierra 100 kilometer away:

> "Using generalized additive models, we found that, after accounting for habitat effects, the probability of *Rana muscosa* presence was significantly reduced by both fish and pesticides, with the landscape-scale effect of pesticides much stronger than that of fish. The degree to which a site was sheltered from the predominant wind (and associated pesticides) was also a significant predictor of *R. muscosa* presence."

Biological and Ecological Impacts

The U.S. EPA review of glyphosate completely misses the mark in terms of acting on the side of caution to protect fish and wildlife and to protect public trust resources. Coupe et al. (2011) noted the following:

> "In spite of the increase in usage across the United States, the characterization of the transport of glyphosate and its degradate aminomethylphosphonic acid (AMPA) on a watershed scale is lacking."

Scientists and academics have plugged some data gaps and characterized the risk to various species. Relyea (2005) conducted controlled experiments with glyphosate-based herbicides in ponds and noted:

> "Collectively, the available data indicate that, contrary to conventional wisdom, current application rates of Roundup can be highly lethal to many species of amphibians. This result is of particular interest in light of the global decline of amphibians (Wake 1998, Alford and Richards 1999, Houlihan et al. 2001, Blaustein and Kiesecker 2002) which, in some cases, is correlated with a proximity to agricultural areas that use pesticides (Bishop et al. 1999, Davidson et al. 2001, 2002, Sparling et al. 2001). Although Roundup is an herbicide, two lines of evidence suggest that the widespread tadpole mortality was directly due to toxicity and not to the destruction of the tadpoles' algal food source. This indicates that Roundup directly kills amphibians rather than indirectly causing amphibians to starve to death."

Battaglin et al. (2005) had the following findings

> "Several studies have documented that some of the surfactants used in glyphosate formulations are more toxic to wildlife than the glyphosate itself (Martinez and Brown, 1991; Mann and Bidwell, 1999; Tsui and Chu, 2003; Howe et al., 2004); however, the surfactants used in glyphosate products were not included in this study. Glyphosate and its surfactant polyoxyethylene amine (POEA) were more toxic to microalgae and crustaceans than to bacteria and protozoa (Tsui and Chu, 2003). Another study reported 'significant effects' of the herbicide formulation on amphibians including a statistically significant reduction in survival of adults."

Another significant finding of Battaglin et al. (2005) was the interaction of glyphosate-based herbicides with predators and the environment. Relyea (2012) found similar effects in the altered shape of frog larvae in the presence of predators and Roundup. His secondary finding was that tadpoles avoided Roundup by swimming to the bottom of ponds, and thereby had less interaction with top-water predators.

Studies of the endangered Lange's metalmark butterfly and its near relative Behr's metalmark butterfly indicate that applications of imazapyr and other herbicides lessened survival of these species at the Antioch Dunes National Wildlife Refuge in Contra Costa County, CA, which is the only known habitat for the species (Stark et al. 2012). Although the agent in the latter case may not have been glyphosate, the decline of the Monarch butterfly is linked to glyphosate. Roundup killed all the milkweed that the caterpillars of the species relied on (FOEE 2013): “It is estimated that common milkweed has been largely eliminated from 100 million hectares of US cropland following the introduction of glyphosate-resistant crops.”

In the soil, earth worms are negatively impacted by glyphosate-based herbicides (Correia and Moreira 2010). Correia and Moreira (2010) found that glyphosate “demonstrated severe effects on the development and reproduction of *Eisenia foetida* in laboratory tests”, which is the most common European earthworm.

Potential Human Health Impacts

As in the realm of environmental effects, U.S. EPA (2017b, 2017c) evaluation of human health risk and glyphosate-based herbicides is also flawed in that the binder POEA and the long-lasting breakdown product AMPA, that both have equal or greater toxicity, are not considered. Recent studies and literature indicate alarming toxicity to human cells from the latter two substances (Defarge 2018).

Stalled by bureaucratic inertia brought on by crushing pressure from Monsanto, the U.S. EPA (2017b, 2017c) is narrowly focused on whether glyphosate-based herbicides caused specific types of cancer as a result of direct exposure (DeRooz et al. 2005). Andreotti et al. (2017) used a larger sampling pool of exposed farmers and their families and was unable to find any significant statistical correlation between glyphosate and any specific cancer. However, of the 44,932 farmers participating in the program and reporting exposure to glyphosate, a total of 5,779 later contracted cancer.

Meanwhile, there is major public health risk because of the casual way herbicides are marketed. Approximately half of the acute exposure reports filed annually are from homeowners mixing pesticides without following instructions (U.S. EPA 2014). Also, 5-27% of exposure cases are children who were exposed, with the route of exposure “accidental ingestion and tampering with the product.” The U.S. EPA (2014) explains why the study of glyphosate was initiated:

> “Given the magnitude and frequency observed in the initial screening evaluation of acute poisoning incidents related to glyphosate use, Health Effects Division determined that a more extensive Tier II report of the acute and chronic human health effects linked to glyphosate use should be performed.”

The International Agency for Research on Cancer (IARC 2015), the cancer-research arm of the World Health Organization, found that glyphosate-based herbicides were likely human carcinogens based on animal tests and potential for cell destruction, DNA disruption, and endocrine disruption. Much recent research has highlighted the substantial human health risk of glyphosate-based herbicides and particularly the degradant AMPA and the binder POEA (Benachour et al. 2007, Gasnier et al. 2009, Mesnage et al. 2013; 2015).

Findings of Gasnier et al. (2009) and Mesnage et al. (2013, 2015) reported above present considerable evidence of negative human health effects because of the toxicity of glyphosate herbicides, especially in combination with the deadly binder POEA.

Gasnier et al. (2009) expressed the following reservations about glyphosate and protection of human health:

> "In addition, these herbicides are spread on most eaten transgenic plants, modified to tolerate high levels of these compounds in their cells. Up to 400 ppm of their residues are accepted in some feed. A real cell impact of glyphosate-based herbicides residues in food, feed or in the environment has thus to be considered, and their classifications as carcinogens/mutagens/reprotoxics is discussed."

Friends of Earth of Europe (FOEE 2013) documented that 44% of people in the EU have some level of glyphosate in their blood stream. They also presented evidence that glyphosate affects the activity of the enzyme acetyl-cholinesterase, which is vital for the operation of the nervous system (FOEE 2013).

U.S. EPA is making its determination of cancer risk on the basis of glyphosate alone, and not measuring co-occurring chemicals and their risk. Therefore, their whole process of evaluation is fundamentally flawed and does not provide the basis for judgement as to whether continuing use glyphosate-based herbicides as presently formulated is prudent.

Glyphosate and the World's Food Production System

Coupe et al. (2011) point out how widespread use of Roundup ready crops are in the United States:

> "More than 90% of the soybeans grown in the United States are glyphosate tolerant, with some states having an even higher percentage, such as South Dakota with 97% and Mississippi with 96% in 2007. In the United States, most of the cotton (72%) and about half of the corn (52%) planted in 2007 were glyphosate tolerant."

The advent of Roundup ready crops now insures an increasing contamination of the of food supply. This is in effect a large, uncontrolled, world-wide experiment with human health. The over-reliance on Roundup ready crops is leading to a major loss of genetic diversity as seeds are proprietary and monocultural. Historic genetic resources for food crops are being lost, a formula for the collapse of the world food supply. Super-weeds that are immune to herbicides are rapidly evolving and will lead to the need for even more toxic substances, yet the U.S. EPA doesn't even address this problem.

Conclusion

The U.S. EPA review of glyphosate-based herbicides is not sufficient to meet the standards of the National Environmental Policy Act (NEPA) or the California Environmental Quality Act (CEQA) because both require examination of all possible related impacts associated with the permitted activity. Since the chemical in question, glyphosate, in its most common formulation Roundup, is always accompanied in the environment by the degradant AMPA and the binder POEA, and both these substances have been found to be more toxic than glyphosate; therefore, the U.S. EPA does not meet the standard for cumulative effects assessment at the ecosystem or human health level for NEPA or CEQA.

It is time that the U.S. EPA gave greater emphasis to consideration of ecological impairment (Vera et al. 2012). The chemicals you are setting up to reauthorize under this review are killing the bees that pollinate plants, the frogs and aquatic biota, and worms and other soil organisms that create living soils. In short, allowing continuing use of these chemicals is killing the ecosystems and soils that support agriculture and human life. The impending agricultural collapse brought on by this chemically dependent monoculture will have huge consequences in terms of human suffering and possibly put our survival as a species at risk.

In terms of human health considerations, it is time that the U.S. EPA switched the burden of proof to chemical companies and acted on the side of caution. Effects of pesticides may be delayed for decades and the diseases that afflict those exposed are never linked to the casual mechanism or the linkage cannot be proved. While the European Union and Canada respond rationally to studies that show human and ecological health risk, banning substances like glyphosate, the U.S. EPA is studying the problems further in order to delay decisions that stop that sale of this extremely lucrative product. This is a pattern of undue influence of money on regulatory over-sight that is preventing protection of public health and leading the collapse of once great ecosystems all across the United States.

The whole construct of U.S. EPA regulation is also completely behind the times with regard to recognizing the synergy of pesticides and herbicides acting in combination that is killing fishes (Leitz et al. 2009) and frogs (Relyea 2005) and causing extensive damage to aquatic biota (Vera et al. 2012). The cumulative effects of pesticides and herbicides are causing unacceptable damage to the environment, sometimes many miles away, and the regulation of individual pesticides has failed.

I urge you not to re-authorize the license for the use of Roundup and make the company pay for monitoring of AMPA and POEA in the environment. If the amount of heavy metals in glyphosate-based herbicides found by Defarge et al. (2018) is routine, then the U.S. EPA must move immediately to have them prevent such toxic contaminants and issue appropriate fines for current heavy metal pollution attendant with use of Roundup.

I respectfully, submit these comments on behalf of the Living Rivers Council. I am available to the U.S. EPA staff for consultation at any time.

Sincerely,

Patrick Higgins
Consulting Fisheries Biologist

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