Fondation David Suzuki
LES SOLUTIONS SONT DANS NOTRE NATURE

équiterre

CAPE Canadian Association of Physicians for the Environment
Association Canadienne des Médecins pour l'Environnement ACME

environmental defence INSPIRING CHANGE

PREVENT CANCER NOW

June 26, 2017

VIA ELECTRONIC MAIL

The Honourable Jane Philpott
Minister of Health
hon.jane.philpott@canada.ca
70 Colombine Driveway
Tunney's Pasture
0906C
Ottawa, ON, K1A 0K9

Dear Minister Philpott,

Re: Notice of Objection to Re-evaluation Decision RVD2017-01, Glyphosate, April 28 2017

Équiterre, David Suzuki Foundation, Canadian Association of Physicians for the Environment, Environmental Defence and Prevent Cancer Now are filing a Notice of Objection to the Re-evaluation Decision RVD2017-01, Glyphosate, announced on April 28, 2017 (hereafter referred to as "Decision"). This Notice of Objection is pursuant of subsection 35(1) of the *Pest Control Products Act* (PCPA), and consists of this letter and attached appendices listed below.

This Notice of Objection is being filed because the PMRA has failed to consider and has dismissed critical evidence in its Decision, with regards to following risks of glyphosate:

- failure to consider critical evidence about glyphosate's impact on milkweed and monarch decline
- failure to consider critical evidence associated with glyphosate's impact on microbiomes - both human and in the soil
- failure to consider critical evidence associated with glyphosate's health impacts, including cancer

- failure to evaluate roles of glyphosate as a chelator, in both soil depletion, and in mobilization of the neurotoxic carcinogen cadmium in grains

Also, the PMRA has failed to consider evidence and has failed to acknowledge critical knowledge gaps in the following risk management strategies included in the Decision:

- failure to consider evidence that demonstrates that riparian buffer strips and buffer zones are inefficient as risk management strategies, particularly concerning efficacy, environmental persistence, and risks to groundwater and surface water contamination
- failure to consider some evidence that shows that labelling may not be an effective strategy to manage risk, and failure to acknowledge large knowledge gaps in the evidence on the efficacy of labelling to manage risks

Because the Decision 1) did not consider or dismissed critical evidence when evaluating the risks posed by glyphosate, and 2) did not consider all evidence and did not acknowledge significant knowledge gaps in the efficacy of risk management strategies, the PMRA's process of re-evaluation is flawed.

Therefore, the Minister cannot determine that glyphosate does not pose unacceptable risks to individuals and the environment as required by the primary objective of the PCPA, 4(1). The Decision should be reviewed by an independent review panel established by the Minister pursuant to section 35(3) of the PCPA.

Attached to this letter are the following documents:

1. Completed forms entitled "Health Canada Notice of Objection under Subsection 35(1) of the Pest Control Products Act" on behalf of each organization filing this Notice of Objection
2. A report prepared by the organizations and scientific advisors that presents the scientific grounds for the Notice of Objection

As guaranteed by the PMRA, the groups reserve the right to make any amendments or additions to this Notice of Objection upon review of the documents requested from the Reading Room. The groups were not able to get access to the Reading Room within the 60 days after the Decision was published because the application form was not available to the public and it took 20 days in total to: receive the appropriate form, be presented with a list of resources for review from the PMRA, and be offered an appointment for the Reading Room. The PMRA has granted an opportunity to submit amendments to this Notice of Objection based on these delays.

Sincerely,

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Scientific Grounds for the Notice of Objection

A. EVIDENCE OF RISKS

1. Failure to consider critical evidence that associates glyphosate with milkweed and monarch decline

The Committee on the status of Endangered Wildlife in Canada (COSEWIC) listed the monarch as a species of “Special Concern” in 1997 and upgraded it to “Endangered” in 2016.

The persistent decline of monarch populations is multifactorial (see Table 1 from Inamine et al. 2016), and includes habitat loss. Of particular concern to the PMRA should be the effects of glyphosate on milkweed, necessary for the monarch’s spring and summer breeding, and on flowering plants which produce nectar, necessary for fall migration.

Table 1. Proposed threats to eastern monarch populations

Proposed threat	References
Habitat destruction/logging at the overwintering sites	Malcolm 1993, Brower et al. 2012b, Vidal et al. 2014
Habitat destruction/reduced nectar availability on southern migration	Alonso-Mejía et al. 1997, Brower et al. 2006
Disease, predation, and parasitoids	Bradley and Altizer 2005, Oberhauser et al. 2015
Climate change/extreme weather	Oberhauser and Peterson 2003, Brower et al. 2012b
Herbicides/genetically modified herbicide tolerant crops (loss of milkweed)	Zalucki and Lammers 2010, Pleasants and Oberhauser 2013, Flockhart et al. 2015
Insecticides/genetically modified insecticidal crops	Krischik et al. 2014
Automobile accidents, especially during the migration	McKenna et al. 2001
Electromagnetic fields/microwave emissions	Guerra et al. 2014
Trap plants	Casagrande et al. 2014, Batalden and Oberhauser 2015

However, the PMRA failed to consider critical scientific evidence regarding the links between intensive glyphosate use and declines in milkweed, nectar-availability, and monarch populations, and consequently failed to integrate necessary mitigation strategies in its Decision.

Though the PMRA states that glyphosate is not supposed to destroy monarch habitats (including milkweed) outside of field limits (p.47, PMRA 2017), scientific evidence suggests that limitations on glyphosate use within a) agricultural regions and b) along roadsides is necessary to protect the viability of monarch populations.

a) Milkweed decline in agricultural regions affect monarch spring and summer breeding grounds

In its northern ranges, the monarch butterfly (*Danaus plexippus*) depends on the common milkweed (*Asclepias syriaca*) for survival. *A. syriaca* generally grows in open habitats, but has suffered massive declines particularly across corn and soy growing regions (Commission for Environmental Cooperation 2008; Brower et al. 2012a; Millet et al 2012; Pleasants and Oberhauser 2012; Flockhart et al. 2013, 2015; Center for Biological Diversity 2014; Jepsen et al. 2015, Zaya et al. 2017). Across the corn and soy belt in the United States midwest, declines in *A. syriaca* have been measured at 81% (Pleasants, 2013) and more recent studies show even more pronounced losses between 93.7% and 96.5% (Zaya et al. 2017).

Zaya et al. (2017) describes the relationship between milkweed decline and the increased use of glyphosate in corn and soy production:

> *"Because milkweeds are highly susceptible to glyphosate herbicides, the connection between A. syriaca declines and glyphosate use is thought to be causal… Supporting the causal role of glyphosate-treatments in these declines, milkweed abundance in two soy fields with a single glyphosate application declined by more than 70% over the season, whereas non-glyphosate treatments in both corn and soy had small to little effect on milkweed abundance (box 1; Pleasants 2015).'' (p.2)*

Milkweed losses as a result of increased glyphosate use in corn and soy production regions are a major contributor to monarch declines, as described by Jepsen et al. (2015):

> *"increased use of the herbicide glyphosate and its detrimental effect on milkweed is almost certainly playing a significant role in the monarch population decline. This impact is magnified as huge amounts of habitat have been – and continue to be – converted to glyphosate-impacted croplands.'' (p.26)*

Several authors reach similar conclusions, and some even state that increases in glyphosate use on herbicide-tolerant crops may eventually lead to the complete disappearance of milkweed in agricultural regions with very consequential effects for monarch populations. For instance, whereas a survey conducted in 1999 of habitats containing a particular milkweed species showed that the number of monarchs produced per hectare (ha) in corn and soy field was as high or higher than that of other habitats (Oberhauser et al, 2001), the rapid adoption of genetically modified glyphosate resistant soy and corn crops after 1999 led to a significant reduction of milkweed and reduced fecundity in monarch females:

> *‘’Much of the combined acreage of soya and maize (60–70 million ha per year) is used in rotation, and this rotation in combination with the high adoption rate of GR (genetically resistant) soya (>70% by 2002, presently 92%) and maize (presently 23%) (U.S.D.A., 2010a) has all but eliminated A. syriaca from 40 million ha of these croplands (Taylor, 2008). Both Hartzler (2010) and J.M. Pleasants (in prep.) have documented the drastic reduction of A. syriaca growing in glyphosate-treated fields in Iowa; Hartzler recorded a 90% loss from 1999 to 2009, and Pleasants measured a 79% loss from 2000 to 2009. We conclude that, because of the extensive use of glyphosate herbicide on crops that are genetically modified to resist the herbicide, milkweeds will disappear almost completely from croplands. Furthermore, Zalucki and Lammers (2010) have estimated with models that the large-scale elimination of milkweeds in agricultural and surrounding landscapes has the effect of increasing the search time for host plants by monarch females with the result that realized fecundity is reduced. ‘’ (p.3 Grower et al. 2012)*

These continental trends suggesting glyphosate’s impact in milkweed decline and subsequent impacts on monarch populations have recently been confirmed at the regional scale. Based on evidence of monarch populations and estimates of the application of glyphosate in corn and soy fields, Saunders et. al. (2017) provides:

> *“...the first empirical evidence of a negative association between county-level glyphosate application and local abundance of adult monarchs, particularly in areas of concentrated agriculture.”*

This decline in monarch counts and glyphosate applications is particularly sharp over the first few years of adoption of glyphosate resistant crops (Figure 1a) 1994-2003 vs b) 2004-2013).

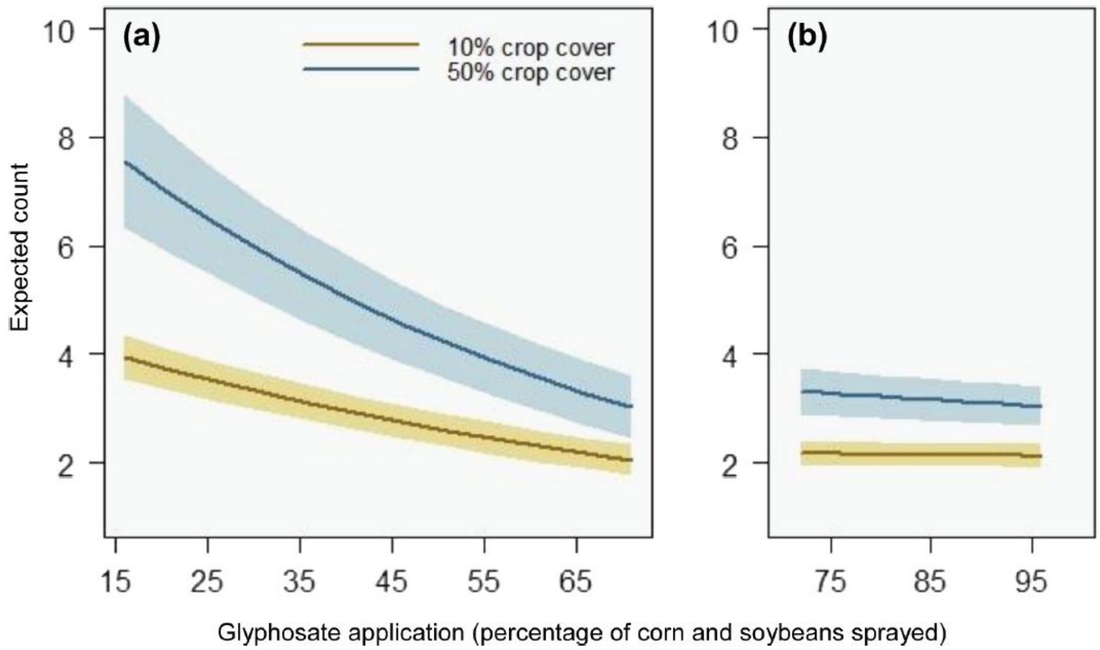

Figure 1 Expected monarch counts declining with increasing glyphosate application, extracted from Saunders et al. 2017.

Because ‘’each milkweed stem in an agricultural field averages 3.9 times more monarch eggs than a milkweed stem in non-agricultural habitats’’ (Pleasants et al. 2017), such significant and precipitous declines in milkweed in agricultural lands is concerning. Pleasants et. al. (2017) argues that between 425 million to 1.6 billion milkweed plants in the monarch breeding grounds would be necessary to reach monarch conservation goals, which means that glyphosate use restrictions in Canada are urgent. Because the PMRA failed to consider this critical evidence making the link between increased glyphosate use, milkweed declines, and monarch declines, the PMRA has failed to propose appropriate risk mitigation strategies to protect monarchs and monarch habitats in its Decision.

Buffer strips are often suggested as habitat protection areas because they support mid-cycle vegetation in corn and soy production regions. However, a recent study in Québec on the effectiveness of riparian buffer strips in protecting biodiversity demonstrated that *A. Syriaca* was not observed on the side of the buffer strip close to the agricultural field but was observed on the center of the buffer strip and on the edge of the stream, where it has an increased chance of being sheltered from glyphosate (Hénault-Ethier, 2016). This research shows that buffer strips could harbour some milkweed to support monarch populations in agricultural areas, but suggests that these habitat protection areas may not be sufficient to support large populations of milkweed to re-invigorate monarch populations. An enlarged no spray buffer zone before the riparian buffer strip could better protect important, marginal milkweed habitat for monarch summer breeding grounds in agricultural regions.

b) Reduced availability of nectar along roadsides affects fall migration

Beyond protecting summer breeding grounds, recent research suggests that sparse autumnal nectar sources in the monarch northern ranges may also be a primary driver for monarch declines (Inamine et al. 2016). Whereas milkweed is essential for monarch breeding in the spring and summer, nectariferous flowers are critical in the fall for transition and migration to overwintering grounds in Mexico. Not only are the "... conditions of the fall migrants … affected by the environment they experience early in life, including milkweed shortage, insecticides, or other changes in habitat quality" (Inamine et al. 2016), roadside maintenance in Canada involves herbicide spraying which limits nectar-producing flowering vegetation along crucial corridors. According to Environment and Climate Change Canada (ECCC) (2014):

> *"The removal of nectar-producing, flowering vegetation along roadsides is a potential threat for the Eastern population of Monarch. For example, mowing, cutting, and spraying of herbicides on roadside vegetation in southern Ontario are standard practices" (p.17)*

ECCC's Monarch management guidelines recommends reducing the widespread use of herbicides along roadsides.

> *''Develop and implement roadside, power line and railway maintenance guidelines or best management practices that conserve and enhance Monarch breeding and nectaring habitat and communicate those with appropriate sectors. These should be regionally and context specific to address timing requirements, invasive species present, species of Milkweed native to that region, and the nature of activities.'' (p.24 Environment Canada, 2014)*

The PMRA's Decision has failed to develop use limitation guidelines consistent with ECCC's monarch management plan. At the very least, the PMRA must integrate the recommendations in the proposed monarch management plan

2014-2019, and cannot defend continued inaction on risk mitigation strategies by calling for further research, especially when strategies have already been proposed by other federal Ministries in Canada.

The information provided may be adjusted upon access to Reading Room data.

2. **Failure to consider critical evidence associated with glyphosate's impact on microbiomes -- for humans and in the soil-- as a patented antibiotic**

Glyphosate is registered as a patented antibiotic and has adverse effects on microbiomes. We note that colorectal cancer is rising rapidly in younger Canadians (Canadian Cancer Society et al., 2017), and that dysbiosis causes increased inflammation that may lead to cancer (Goodson et al., 2015). A review of the data included in the Reading Room is necessary for further comment on the human health microbiome effects.

Soils in organic agriculture typically contain more carbon and a greater diversity of bacterial species that break down organic matter. This observation is frequently made by farmers converting from agriculture that is highly dependent on synthetic pesticides, including glyphosate (Lynch, 2009). Repeated glyphosate application results in a shift to fungal species breaking down plant material, and with this a serious increase in aflatoxins. Arnason (2017) recently reported that aflatoxin problems are escalating among farms that use synthetic pesticides on grains but are a rarity among organic farms. The solution to aflatoxin contamination has perversely been to increase spraying of glyphosate pre-harvest, to encourage more rapid dry-down. The PMRA has failed to consider evidence of the effects of glyphosate on the soil microbiomes and has not imposed risk mitigation and reduction strategies necessary to protect the soil microbiota, while indicating that this topic is beyond the scope of pesticide assessment (section 2.2.3).

3. **Failure to consider critical evidence associated with glyphosate's impact on human health, including cancer**

It is difficult to determine from the unpublished references in the Decision what evidence has been considered on cancer. The arguments below are presented without access to the Reading Room, and may be adjusted based on the information gathered at the Reading Room.

a) Cancer

From our analysis of the final decision document, the PMRA didn't include statistically significant cancer findings in its assessment of the carcinogenic potential of glyphosate.

Dr. Christopher Portier is the former Director at the US National Center for Environmental Health; former Director at the US Agency for Toxic Substances and Disease Registry; former Associate Director as the US National Institute of Environmental Health Sciences; former Associate Director at the US National Toxicology program; and a fellow at the American Statistical Association and the International Statistics Institute.

Dr. Portier presented his analysis of raw data from animal cancer studies partially released under a public access request in an open letter dated May 28, 2017 to the President of the European Commission, Jean Claude Juncker.

Dr. Portier found eight *"significant increases in tumor incidence that do not appear in any of the publications or government evaluations presented by both EFSA and EChA".* According to Dr. Portier, *"Some of these tumors were also present in multiple other studies increasing the consistency of the findings across studies."* For Dr. Portier, this *"suggests that the evaluations applied to the glyphosate data are scientifically flawed, and any decisions derived from these evaluations will fail to protect public health."* The PMRA relies on the EFSA's finalized re-assessment of glyphosate in the Glyphosate Re-evaluation Decision but does not note the underlying scientific flaws identified by Dr. Portier.

Dr. Portier asks *"that the evaluations by both EFSA and EChA be repeated for all toxicological endpoints and the data underlying these evaluations be publicly released."* Portier also studied 13 other statistically positive findings for tumor sites.

From these 21 studies of glyphosate identifying positive tumor findings, the PMRA only included 3 as shown by the comparison table below (Table1).

Table 1*.

Reference	Taken into account in the PMRA assessment	Conclusion rejected by the PMRA
Atkinson, C., Strutt, A., Henderson, W., et al. (1993a). 104- Week Chronic Feeding/Oncogenicity study in rats with 52-week interim kill. MRID No. 49631701. Unpublished	YES	YES
Atkinson, C., Martin, T., Hudson, P., and Robb, D. (1993b). Glyphosate: 104 week dietarycarcinogenicity study in mice. Inveresk Research International, Tranent, EH33 2NE, Scotland. IRI Project No. 438618. April 7, 1993. MRID 49631702. Unpublished.	YES	YES
Brammer. (2001). Glyphosate Acid: Two Year Dietary Toxicity and Oncogenicity Study in Wistar Rats. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK: Syngenta. MRID 49704601. Unpublished.	YES	YES
Enemoto, K. (1997), HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol. 1. The Institute of Environmental Toxicology, Kodaira-shi, Tokyo, Japan, Arysta LifeSciences, Study No.:IET 94-0150. MRID 50017104, 50017105, 5001703. Unpublished.	NO	Not applicable

Knezevich, A.L and Hogan, G. K. (1983). A chronic feeding study of glyphosate in mice. Unpublished report prepared by Bio/Dynamic Inc., dated July 21, 1983. Report No. 77-2011.EPA Accession No. 251007 – 251009, and 251014. EPA Accession no. 251007-09, 251014. Unpublished.	NO	Not applicable
Kumar, D.P.S. (2001), Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice, Toxicology Department Rallis Research Centre, Rallis India Limited. Study No. TOXI:1559.CARCI-M. MRID 49987403. Unpublished.	NO	Not applicable
Lankas, G, P. (1981) A Lifetime Study of Glyphosate in Rats. Report No. 77-2062 prepared by Bio Dynamics, Inc. EPA Accession. No. 247617 – 247621. December 23, 1981. MRID 00093879. Unpublished.	NO	Not applicable
Sugimoto, K. (1997), HR-001: 18-Month Oral Oncogenicity Study in Mice, Vol. 1 and 2. The Institute of Environmental Toxicology, 2-772, Suzuki-cho, Kodaira-shi, Tokyo, 187, Japan, Study No.:IET 94-0151. MRID 50017108, 50017109. Unpublished.	NO	Not applicable
Wood, E., Dunster, J., Watson, P., and Brooks, P. (2009a) Glyphosate Technical: Dietary Combined Chronic Toxicity/Carcinogenicity Study in the Rat. Harlan Laboratories Limited,Page 156 of 227 Shardlow Business Park, Shardlow, Derbyshire DE72 2GD, UK.	NO	Not applicable

Study No. 2060-012. April, 23, 2009. MRID 49957404. Unpublished.		
Wood, E., Dunster, J., Watson, P., and Brooks, P. (2009b) Glyphosate Technical: DietaryCarcinogenicity Study in the Mouse. Harlan Laboratories Limited, Shardlow Business Park, Shardlow, Derbyshire DE72 2GD, UK. Study No. 2060-011. April, 22, 2009. MRID 49957402. Unpublished.	NO	Not applicable

** It may be that some of these studies were dismissed by the PMRA because the NOAELs determined are above that used in the Glyphosate re-evaluation but the re-evaluation decision does not provide reasons so they are all included in the Table above. It may also be that some of these studies are included in the PMRA's re-evaluation decision as unpublished references, but it is difficult to compare without complete identifiable bibliographic reporting by the PMRA and/or a review in the Reading Room. In any case, cancer is frequently considered a non-threshold outcome, so all evidence should be included and considered, possibly in a meta-analysis.*

Dr. Portier also indicates his concerns, "that other areas of the EFSA review (e.g. reproductive toxicity and endocrine disruption) may have also received inadequate evaluations. Since the industry-supported scientific evidence is not available to external scientists, I am unable to evaluate these data and determine if there are positive findings that escaped detection. I encourage you to release these data for external analysis and review as well." Our organisations share Dr. Portier's concerns, and will review additional unpublished data once available from the Reading Room. The period of 60 days after the Decision was posted did not offer sufficient time, particularly because the links for the application form were not available to the public and the PMRA did not respond in a timely fashion to provide access.

Finally, Dr. Portier raises several major concerns "that have not been adequately addressed in the final assessments and should again be addressed appropriately. These are:

- the classification of the human evidence as "very limited" is not a valid characterization under the CLP guidelines and fails to properly address that

- both EFSA and EChA dismissed positive findings because they fell inside of the range of the historical controls (this is an improper use of historical control evidence);
- both EFSA and EChA compared findings across different strains and different study durations to conclude that studies were inconsistent (this is not scientifically justifiable);
- both EFSA and EChA characterize the evidence for genotoxicity as negative, yet a careful review of the evidence released by EFSA and the open scientific literature suggest there are many guideline and non-guideline studies demonstrating genotoxicity." The PMRA has not noted any genotoxic potential for glyphosate.

b) Impact of co-formulants

From our analysis of the proposed and final decision documents, the PMRA did not assess the toxicity of commercial formulations in its re-evaluation. The PMRA states that, although the majority of toxicity studies of glyphosate on mammals have been conducted with the active ingredient (glyphosate acid), the PMRA has also examined toxicological studies that have evaluated the acute risk of preparations. The PMRA has not assessed the chronic risk of commercial formulations containing glyphosate.

Yet, the PMRA recognizes that certain studies done with commercial formulations containing glyphosate suggest that certain formulations are genotoxic, while studies that cover only the active ingredient don't reveal this adverse effect, and recognizes that this effect could be due to a component other than the glyphosate acid in these commercial formulas. Despite this acknowledgement, the PMRA claims that studies conducted with glyphosate alone are more relevant to characterize its toxicity, than studies that have been conducted on other unidentified components, the composition of commercial formulas being exclusive data to the registrant, and purportedly different from one country to another. The PMRA states that the composition of all registered pest control products in Canada are disclosed to the PMRA and toxicity data are also required for each product that is being assessed in the pre-market evaluation process. We thus understand that the PMRA relies on data dating from the pre-market evaluation process to evaluate other components of commercial formulations. This approach risks putting aside the scientific knowledge of recent years on the adverse effects of components of commercial formulations other than the active ingredient.

This PMRA's approach raises concerns, given that an increasing number of studies reveal the toxicity of other components in the commercial formulation beyond just the active ingredient. For instance, a comparison of the toxicity of different brands of glyphosate-based herbicides in tissue culture cell assays showed that several commercial formulations were up to one thousand times more toxic than glyphosate (Mesnages et. al 2014). Other studies have also demonstrated that the surfactant polyoxyethylene tallow amine (POEA), one component of the adjuvant mixture present in some glyphosate-based herbicides, was ten thousand times more cytotoxic than glyphosate itself when applied to human tissue culture cells (Mesnages et al. 2013). These results challenge the establishment of guidance values such as the acceptable daily intake of glyphosate, because these are based on tests conducted with glyphosate alone (Mesnages et al. 2013).

Although the PMRA states that it has evaluated POEA and even cites the studies mentioned above, it appears as though the PMRA didn't actually assess the toxicity of POEA. It appears that this evaluation consisted only of the acknowledgement that POEA is among formulants classified in List 4B, a list composed of formulants of minimal concern, and relied on the EPA assessment of POEA. The EPA has evaluated the risks for human health of ATAE, a sub-family of POEA, and the PMRA has examined the toxicity studies available that have been taken into account in the EPA evaluation. The EPA claims that the commercial products that contain less than 20% of POEA by weight are not of concern. According to the PMRA, all commercial products containing glyphosate currently in Canada meet this limit. The PMRA didn't present how it ensures that the EPA has taken into account all data on the subject, has taken into account the most recent results (such as the Mesnage, R., Bernay, B., et al., 2013 study mentioned before) and did a credible evaluation. Meanwhile, scientists from around the world are urging regulatory bodies to scientifically assess commercially used formulations, because herbicide mixtures likely have effects that are not predicted by assessing glyphosate alone (Vandenberg et al. 2017; Peterson et al. 2016), as stated by Mesnage R, Defarge N, Spiroux de Vendômois J, et al. (2015):

> *"In addition, the real and various mixtures of GlyBH [glyphosate-based herbicides] to which we are exposed have not*

been scientifically assessed by regulatory agencies. Adjuvants (such as POEA) amplify the toxicity by increasing glyphosate uptake in cells, or by adding their own toxicity through cell membrane disruption. … The exposure of animals at doses ranging from 1 to 10 mg/kg bw per day to 5000 or even 10,000 mg/ kg bw per day during their whole life is not relevant to conclude on the effects of exposures in the range of 10-100 mg/kg bw per day. Major endpoints of toxicity for both Roundup and glyphosate, such as developmental, reproductive, transgenerational and even chronic effects on adults, still need to be investigated at relevant doses, at which endocrine disrupting effects may arise. The lack of investigation of low dose chronic effects and the neglect of non-monotonic dose-response relationships make the safety conclusions below 50 mg/kg bw/d of glyphosate questionable. The first and minimal assessment would be to test the chronic toxicity/carcinogenicity of glyphosate at its ADI over the whole life of a mammal, including a prenatal period exposure.

"Before awaiting further mandatory and independent chronic assessment of pesticide formulations including Roundup, this large discrepancy should be borne in mind when forming policies for the protection of public health. Overall in the current regulatory assessment, any toxic effect is first suspected to be a false positive, arising by chance, rather than questioning whether no evidence of effect is a false negative result. We encourage regulators to ask for a complete re-evaluation of glyphosate formulations rather than glyphosate alone, taking into account loopholes in the current assessment."

The NOAEL used by the PMRA for all populations and durations is 32/34 (male / female) mg/kg bw/day (chronic / carcinogenicity study in rats). It is the lowest NOAEL used by the PMRA.

We thus ask that the PMRA evaluate the chronic health impact with co-formulants included in all commercial formulations containing glyphosate registered in Canada.

c) Other health effects

A literature review listed in the PMRA final decision document revealed a coherent body of evidence indicating that glyphosate-based herbicides could be toxic below the regulatory lowest observed adverse effect level for chronic toxic effects. It includes teratogenic, tumorigenic and hepatorenal effects.

Some effects were detected in the range of the recommended acceptable daily intake (ADI) of 0.3 mg/kg bw/d (which is the same as the one used by the PMRA). The literature review indicated that toxic effects of commercial formulations can also be explained by glyphosate-based herbicides adjuvants, which have their own toxicity, but also enhance glyphosate toxicity. These challenge the assumption of the safety of glyphosate-based herbicides at the levels at which they can be found in food and the environment, although these levels may fall below regulatory thresholds. The authors of the review state:

> *"Neurodevelopmental, reproductive, and transgenerational effects must be revisited, since a growing body of knowledge suggests the predominance of endocrine disrupting mechanisms caused by environmentally relevant levels of exposure."*

- Hepatorenal

Three studies not included in the PMRA final decision document reported hepatorenal changes below the ADI of 0.3 mg/kg bw/d (which is the same used by the PMRA) at levels relevant for environmental exposures (Larsen et al. 2014).

- Hepatotoxic

One study listed in the PMRA final decision document suggested irreversible damage in hepatocytes below 5 mg/kg bw/d (Benedetti et al. 2004). In this study, *"glyphosate administered to rats at a concentration of 4.87 mg/ kg bw glyphosate every 2 days over 75 days induced hepatic leakage of ALAT and ASAT, suggesting irreversible damage in hepatocytes."* Yet, the NOAEL used by the PMRA for all populations and durations – which is the lowest NOAEL used by the PMRA - is 32/34 (male / female) mg/kg bw/day. It is concerning to see that the lowest NOAEL used by the PMRA is more than 6 times the concentration at which hepatotoxicity has been reported.

- Reprotoxic

Studies listed in the PMRA final decision document report reprotoxic effects below the lowest NOAEL used by the PMRA. One study reported puberty delay and alteration of the functions and structure of testes from 5 mg/kg bw/d (Romano et al. 2010). In other peer-reviewed studies that have exposed rats *in utero*, Roundup altered spermatogenesis from 6 mg/kg bw/d and disrupted serum testosterone levels in the adults (Dalegrave et al. 2007). Another study (Romano et al. 2012) found that maternal exposure to glyphosate-based herbicides (50 mg/kg bw/d) disturbed the masculinization process and promoted behavioral changes, as well as histological and endocrine problems, with consequences to the reproductive parameters of the progeny. It is concerning to see that the lowest NOAEL used by the PMRA is many times higher than the concentration at which reprotoxicity has been reported.

- Teratogenic

Studies listed in the PMRA final decision document report teratogenic effects below the NOAEL used by the PMRA. *"Visceral and skeletal malformations arose from 20 mg/kg bw/d in regulatory studies"* (Antoniou, 2012).

> *"Evidence of teratogenicity was found in the German authorities' draft assessment report on the industry studies that underlie the authorization of glyphosate in the EU (Antoniou, 2012). The lowest dose of glyphosate alone producing an effect led to the decrease in the mean litter size from 7.7 mg/kg bw/ d in a two-generation rat reproductive study (German Federal Agency CPFS, 1998). This was not found in the F2 generation. In a second developmental study, a statistically significantly increased number of fetuses with a dilated heart was found at the lowest dose of 20 mg/kg bw/d, while no fetus was affected in the control group"* (German Federal Agency CPFS, 1998).

Again, it is concerning to see that the lowest NOAEL used by the PMRA is many times higher than the concentration at which reprotoxicity has been reported.

4. Chelation effects on nutrient and toxicant levels in soils and foods

Glyphosates binds (chelates) vital minerals in soils and plants, mobilizing them into the aqueous phase. This leads to depletion of essential minerals, and also to mobilization of less soluble toxic heavy metals. Thus, crops treated with glyphosate may contain higher levels of the neurotoxic carcinogen cadmium (Barański et al. 2014). Cadmium (Cd) is hyperaccumulated in grains, and although Canada has no standard for cadmium in grain, this is monitored by the Grain Commission for compliance with international standards. Excessively contaminated Canadian wheat has previously been sent back from Europe. High Cd levels in Canadian potash used in fertilizers exacerbate this problem that originates in naturally high Cd levels in prairie soils.

The PMRA decision document stipulates that ramifications of chelation are beyond the scope of pesticide assessment, in spite of the chemical having been patented for this capability.

B. RISK MITIGATION

1. **Riparian buffer strips (RBS) and buffer zones are inefficient as risk management strategies, considering efficacy, environmental persistence, and risks of groundwater and surface water contamination**

In the Proposed and Final decisions on glyphosate registration, the PMRA states:

> *"Glyphosate formulations pose a negligible risk to freshwater fish and amphibians, but may pose a risk to freshwater algae, freshwater plants, marine/estuarine invertebrates and marine fish if exposed to high enough concentrations. Hazard statements and mitigation measures (spray buffer zones) are required on product labels to protect aquatic organisms." (p.13, PMRA, 2015)*

> *"The environmental assessment concluded that spray buffer zones are necessary to mitigate potential risks to*

non-target species (for example, vegetation near treated areas, aquatic invertebrates and fish) from spray drift. " *(p.6, PMRA, 2017)*

"In the terrestrial environment the only risk identified was for terrestrial plants, therefore, spray buffer zones are required to reduce exposure to sensitive terrestrial plants." (p.6, PMRA, 2017)

These statements implicitly assume both that there is a potential risk posed to non-target species and that no-spray buffer zones are an effective mitigation strategy. However, PMRA fails to provide scientific evidence supporting the efficiency of buffer zones in mitigating glyphosate leaching to aquatic ecosystems.

Few authors have studied glyphosate runoff through riparian buffer strips (RBS). One of the few studies conducted on the topic, Lin et al. (2011) observed a 60–71% reduction in glyphosate leaching through 4–8 m wide RBS composed of *Festuca arundinacea*, *Festuca* and *Panicum virgatum*, and native *Tripsacum dactyloides* plants. These scientists relied on a homogeneously distributed runoff simulation (using a rotating boom), which makes the result of this experiment unlikely similar to natural heterogeneous settings that occur in the fields. Their study suggests that larger RBS may be effective than narrower ones in trapping sediment bound glyphosate.

In another study, Syversen and Bechmann (2004) concluded that glyphosate-removal is relatively low in terms of efficiency across the RBS (mean: 39%; range approximately from 10-75%). Soluble glyphosate removal efficiency (measured on centrifuged samples) is relatively low (mean 42%; range 24-70%) and these authors indicate that further investigation of the poorly documented potential of the RBS is warranted. Importantly, according to these authors, RBS removal efficiency for glyphosate may be lower compared to other pesticides.

Syversen and Bechmann (2004) analyzed glyphosate retention in 5m wide Norwegian RBS composed of various grasses (*Circium arvense* (L.) Scop., *Elytrigia repens repens* (L.) Desv. Ex Nevski, *Phleum pratense pratense* (L.), *Deschàpsia cespitòsa cespitòsa* (L.) Beauv, *Festuca pratensis* Huds.). They relied on surrogate runoff in short-term experiments (5h), and a homogeneous runoff distribution system (perforated gutter). Such settings are hardly representative of heterogeneous natural precipitations and the heterogeneity of natural runoff in a field (Hénault-Ethier, 2017b). Glyphosate was added to a soil and water mixture with total concentrations representing 12-23 µg/g soil. If the glyphosate concentrations used (equivalent to 12 000 – 23 000 µg/Kg of soil in the aqueous mixture in Syversen and Bechmann (2004)) are compared to the soil glyphosate concentrations measured in Québec soils, there is a two order of magnitude difference (mean : 210 µg/Kg, range: 0-317 µg/Kg; Hénault-Ethier, et al. 2017a). Not only are the glyphosate reduction observations of Syversen and Bechmann (2004) study inconsistent with those observed in Québec (Hénault-Ethier, et al. 2017a), the methodology used also strongly reduces the applicability of the results to real life conditions in Canadian fields, and may thus invalidate the conclusions of the study.

In an earlier study, Syversen (2003) suggested high glyphosate (74%) and AMPA (78%) retention efficiency, under natural precipitation conditions in Norway. However, controls consisted of reference plots which were parallel to treatment plots with a RBS (as opposed to measuring before and after on a single RBS), and the authors noted a difference in runoff between the treatment and control plots. This experimental design has several limitations (Hénault-Ethier, 2016; Hénault-Ethier, 2017b). Hence, their conclusions may not be generalizable.

On the other hand, the most recent Canadian scientific findings suggest that vegetated buffer strips have only a very low or weak potential efficiency to minimize glyphosate and AMPA leaching via runoff (Hénault-Ethier, et al. 2017a). Although RBS studies on nutrients commonly suggest that wider RBS have higher removal efficiency, the narrow RBS width promoted by the Quebec provincial government could explain their limited efficacy. However, several other factors could also be involved. Among these, high phosphorous loads from fertilization may compete for adsorption sites on soils and induce leaching of glyphosate after fertilization, which may be independent of the width of the RBS.

This new research also shows that measuring soil glyphosate concentration before and after a RBS is not sufficient to determine the efficacy of buffer zones to intercept dissolved glyphosate (Hénault-Ethier, et al. 2017a). If RBS are inefficient at intercepting dissolved glyphosate, studies demonstrating the efficiency of RBS at intercepting unfiltered runoff (i.e. Syversen & Bechman, 2003) or particle bound glyphosate (i.e. Lin et al. 2011) may overestimate the potential efficiency to minimize glyphosate transport. This relationship is revealed through the correlation of an increasing pesticide removal efficiency with an increasing particle concentration in runoff (Syversen & Bechman, 2003).

In its final decision, PMRA further states that:

> *"Runoff events can be difficult to predict and the presence of glyphosate in water as a result of runoff or spray drift is expected. Proper application timing and runoff/spray drift mitigation measures can reduce potential impacts." (p.49, PMRA, 2017)*

No scientific evidence is provided by the PMRA to support the runoff/spray drift mitigation measures to reduce potential impacts. This statement appears contrary to novel evidence:

> *"3-m-wide RBS, even with the use of fast growing willows as efficient phytoremediation agents instead of spontaneous herbaceous vegetation, do not significantly decrease aqueous glyphosate and AMPA leaching in runoff waters." (p.8, Hénault-Ethier et al. 2017a).*

The low intrinsic efficiency of RBS may not be the only limitation of buffer zones as a risk mitigation measure. RBS adoption rates by farmers should also be considered by the PMRA in its final decision. The PMRA states:

> *"Over the last two decades, Canadian growers have adopted best management practices on their farms (such as hedgerow, riparian strip, grass farm road, implementation of no till techniques leaving more plant biomass on the ground for runoff interception as well as the use of buffer zones) to avoid soil, fertilizer and pesticide losses from fields." (p.49, PMRA 2017)*

Though these recommended practices are being increasingly adopted, they are by no means ubiquitous in farming regions. Non-compliance for buffer zone implementation in riparian areas is heavily documented in Canada (see Dagenais 2016 and references therein including Sager (2004)). Only 53% of Québec municipalities require riparian buffer strips in their regulations, and some others require a permit to cultivate in the riparian zone. This is contrary to the *Politique de protection des rives, du littoral et des plaines inondables* of Québec, which recommends variable minimal RBS widths depending on the context.

Prescribed RBS widths are not often accepted by farmers (Dagenais, 2016), because they feel frustrated by the negative impacts, including economic impacts, of establishing and maintaining RBS, and therefore may not adopt RBS recommendations or maintain them (Belzile et al. 2013). Belzile et al. (2013) study suggests that farmers who implement RBS may even be negatively stigmatized by their peers for favoring riparian plant growth. The PMRA does not consider this evidence and the barriers to farmer compliance in its risk mitigation strategy.

The PMRA also failed to consider scientific evidence concerning glyphosate's potential to leach into groundwaters. The PMRA states that:

> *"Monitoring studies conducted throughout Canada indicate that glyphosate is rarely detected in groundwater. Although glyphosate is often detected in surface water, the concentrations detected are at relatively low levels that do not pose a risk of concern." (p.49, PMRA 2017)*

However, a new scientific study conducted in Québec suggests that RBS, which are designed to control runoff, may increase glyphosate infiltration in groundwater (Hénault-Ethier, et al. 2017a). This new study in Quebec echos similar concerns expressed by others (Krutz et al. 2005).

> *''Potential glyphosate drainage and groundwater contamination potential is theoretically considered low (Cerdeira and Duke, 2006; Gustafson, 1989; Horth and Blackmore, 2009; Scribner et al., 2007) because of potential glyphosate sorption on soil particles (Vereecken, 2005; Wauchope et al., 2002). Despite this fact, high water solubility (12.0 g·L−1; pH 4.3, 25 °C) (EPA, 2009b) may permit glyphosate infiltration under conditions of high precipitation, and especially in the presence of preferential flowpaths, such as macropores (Kjaer, 2005; Vereecken, 2005).'' (p.7 Hénault-Ethier, et*

al. 2017a)

Evidence suggests that once in groundwater, glyphosate may become persistent, and this is not considered by the PMRA in its Decision which describes it as ''non-persistent to moderately persistent''.

> *"Common conditions in riparian interstitial or groundwater such as darkness (Mercurio et al., 2014), anaerobic conditions (EPA, 2009b), cold (Helander et al., 2012) and salty environments (Yang et al., 2013), may increase glyphosate persistence." (p.8 Hénault-Ethier, et al. 2017a)*

Hence, in the long term, it is likely that glyphosate contamination would accumulate. The rare detections of glyphosate in Canadian groundwater may be due to low sampling size; glyphosate is known to be present in groundwaters in Europe.

> *"Horth and Blackmore (2009) reported glyphosate detection in 1.7% of 28,000 groundwater samples from 8000 sites between 1993 and 2008 in Europe (>0.1 $\mu g \cdot L^{-1}$ in 0.9% of the samples)." (p.8 Hénault-Ethier, et al. 2017a)*

New Canadian (Québec) based evidence suggests that glyphosate applied in June persists at least until the following spring in soils and runoff waters and concentrations of glyphosate equal to those measured during leaching soon after field spraying may be measured the following spring, after sowing and fertilisation (Hénault-Ethier, et al. 2017a). This directly contradicts the PMRA (2017) observation that glyphosate is ''not expected to carry over to the next year'' (p.48). This new Canadian evidence needs to be considered by the PMRA (2017), which dismissed similar persistence conclusions from American studies (Battaglin et al. 2014), on the basis that Canada has different ecoregions, climate and soils than the US.

Scientific evidence demonstrates an increasing trend in the frequency in which glyphosate is detected in surface waters of rivers monitored in Québec's agricultural regions (Giroux, 2015; Giroux and Pelletier, 2012), but this evidence is not considered by the PMRA. New scientific literature reviews suggest that:

> *"Biodiversity and productivity of aquatic communities may*

be impacted by glyphosate … not only at concentrations below the Canadian chronic aquatic toxicity criteria which was recently augmented to 800 μg·L^{-1} by the Canadian Council of Ministers of the Environment (CCME (Canadian Council of Ministers of the Environment), 2012) but also below the 65 μg·L−1 threshold currently in effect in Quebec (Giroux, 2015)." (Hénault-Ethier, et al. 2017a).

A Canadian study by Smedbol et al. (2013) was not considered in the Final decision, and demonstrated changes in phytoplankton assemblages at 5 μg·L^{-1} in surface waters. Furthermore, another study demonstrating that antioxidant enzymes (catalase, ascorbate, peroxidase, superoxide dismutase) increase after 24h at ≥ 300 μg/L, by Chesney et al. (2015) was not taken into account in the Decision.

Concerning recommendations specific to formulations and their effects on the environment, the PMRA concludes that:

"Certain glyphosate formulations include a surfactant composed of POEA compounds. At high enough concentrations, POEA is toxic to aquatic organisms but is not expected to remain in the environment. While, in general, glyphosate formulations that contain POEA are more toxic to freshwater and marine/estuarine organisms than formulations that do not contain POEA, they do not pose risks of concern to the environment when used as directed on the label." (p.49)

However, the no-spray buffer zones required by the PMRA for other glyphosate formulations is not increased in presence of the POEA co-formulants. The risk mitigation strategy required by the PMRA for formulations containing POEA thus appears inconsistent with the fact that in general, glyphosate formulations that contain POEA are more toxic to freshwater and marine/estuarine organisms than formulations that do not contain POEA.

Indeed, the required buffer zones for the protection of aquatic habitats is one meter for agricultural crop systems and ground boom application methods, as well as in forest systems and non-crop systems. The Buffer Zone is increased to 15, 20 or 25 meters for aerial or airblast applications in agricultural crop, pasture and turfgrass systems. Only in rights of way areas of non-crop land and industrial uses are the Buffer Zones increased to 60 or 100m. For formulations containing the co-formulant POEA, the required buffer zone to protect aquatic habitats is not increased sufficiently.

Concerning the width of buffer zones, the recommended widths proposed by PMRA appear insufficient, as 3m RBS were inefficient to mitigate glyphosate leaching to surface waters (Hénault-Ethier et al. 2017a).

Weed field communities are voluntarily impacted by herbicides, but plants may involuntarily be impacted with the occasional drift to non-target habitats (Gomes et al. 2014) which may reach 10% of the sprayed volumes (see Jobin et al. (1997), and references therein). Herbicide spray drifts are generally considered negligible beyond 10-15 m in opened areas (no vegetation) under light to moderate winds (compiled by Gove et al, (2007), but may reach as far as 30m in forested areas abutting fields (Elliot, 1983). Agricultural habitats are known to be impacted by herbicides in Canada, an impact that influences the species composition of fields and contiguous areas (Jobin et al, 1997). This impact has been evidenced on transects as short as 10m, crossing midway the field and the uncultivated zones. The various herbicides included in these studies (i.e. atrazine, metolachlor, dicamba and glyphosate) were responsible for a reduction in Shannon diversity (a diversity measurement index).

2. Efficacy of labelling as a risk management strategy: Knowledge gap not acknowledged by the PMRA

In the PMRA's Decision, it is stated that "the PMRA is granting continued registration of products containing glyphosate with requirements of additional label updates to further protect human health and the environment.'' The PMRA does not provide *any* scientific grounds to defend that labelling is an effective risk management strategy in the protection of human health and the environment from unacceptable risks.

The PMRA should, at the very least, acknowledge that there is a significant knowledge gap as it concerns the efficacy of labelling as a risk management strategy. The PMRA should also acknowledge that the limited research that does exist indicates that, in other contexts, precautionary statements on labels are often not interpreted correctly by users (Rother 2008). For many users, the very fact that a product is marketed is seen as evidence of its safety, and labels are viewed as information overload. Further, illiteracy, poverty and a perception that exposure to pesticides is an inevitable part of a farm workers work results in limited adoption of safety precautions while using and storing pesticides (Kiriaki et. al 2014).

Relying on labelling as a risk mitigation strategy puts the onus on individuals and leaves important gaps in the protection of Canadians' health and environment. This strategy should not be relied upon until a robust, independent evaluation of the effectiveness of precautionary label statements be conducted within the Canadian context, and must include migrant agricultural labourers as part of the sample, considering significant language and cultural barriers. This study is needed in order to understand if those applying pesticides in Canada read and understand precautionary label statements, and if the vast majority of them ultimately follow the instructions on the label intended to reduce risks. Until then, the PMRA must acknowledge the knowledge gap in the efficacy of of labelling as a risk management strategy, and this must be clearly stated in the Decision so that Canadians know that this risk management strategy is not based on scientific grounds.

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