June 12, 2015

Via e-mail to ***Minister_Ministre@hc-cs.gc.ca***

The Honourable Rona Ambrose
Minister of Health
Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
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Dear Minister Ambrose:

Re: Proposed Re-evaluation Decision PRVD2015-01 – Glyphosate

These comments are submitted jointly by Canadian Association of Physicians for the Environment, Canadian Environmental Law Association, David Suzuki Foundation, Ecojustice Canada, Friends of the Earth Canada, Ontario Nature and the Wilderness Committee. While our organizations have diverse

mandates, we all seek to conserve biodiversity, restore environmental quality and promote human health for Canadians.

We submit these comments pursuant to section 28 of the *Pest Control Products Act,* SC 2002, c28 ("the *PCPA*").

In these comments, we summarize our serious concerns with the Proposed Re-evaluation Decision PRVD2015-01 dated April 13, 2015 ("Proposed Glyphosate Decision").

The Proposed Glyphosate Decision has been issued at the end of a lengthy re-evaluation, initiated many years ago under section 16 of the *PCPA.* Over the last seven years, Health Canada's Pest Management Regulatory Agency (the "PMRA") has conducted this re-evaluation largely in private, without inviting any public participation to date.

Further, the PMRA has not, to date, provided Canadians with information related to its glyphosate re-evaluation that it is required by law to make publically available. Specifically, the PMRA has not yet complied with ss. 42(2)(c) and 42(7), insofar as the electronic registry does not yet contain the all of the information, in respect of each registered pest control product containing glyphosate, provided by the registrants for the purposes of this re-evaluation. Likewise, the PMRA has not yet disclosed on its electronic registry the information that it considered under s. 19(1)(c) in its re-evaluation, which is contrary to s. 42(2)(e).

Additionally, we cannot find any notices delivered under s. 19(1)(a), which are issued in the course of the PMRA conducting a re-evaluation to ask the registrants to provide any additional information that the Minister considers necessary – although perhaps this is because the PMRA chose not to issue any such notices in this re-evaluation. Just by way of example, despite that a Committee on the Status of Endangered Wildlife in Canada ("COSEWIC") Assessment and Status report on the status of Monarchs in Canada, published in 2010, identified the use of herbicides (including those related to Roundup Ready crops) as a threat to the survival and recovery of Monarchs, it appears that the PMRA did not ask the registrants to provide additional information about this threat.

Having conducted a re-evaluation of the controversial herbicide glyphosate, the PMRA is proposing to continue the registration of every end-use product that contains glyphosate, for ongoing sale and use in Canada. The only proposed conditions of registration are minor risk reduction measures relating to product labels.[1]

Overall, our concern is that your Proposed Glyphosate Decision threatens Canadians' health with unacceptable risks. Further, we have equally serious concerns with respect to the unacceptable environmental risks of the Proposed Glyphosate Decision on the environment, including at-risk Monarch butterflies and plant species that they depend upon.

[1] Human health: restriction on entering site for 12 hours after use in agricultural areas. For bystanders statement regarding drift. Environment: warning regarding non target species, spray buffer zones to protect non target species and aquatic habitat, and measures to protect runoff.

1) Canadians are highly exposed to products containing glyphosate

Glyphosate is a non-selective herbicide widely registered in Canada for numerous uses. End-use products containing glyphosate are registered for uses on forests and woodlots, industrial oil seed and fibre crops, terrestrial feed and food crops, industrial and domestic vegetation control non-food sites, ornamentals outdoors and turf. Further, seeds that have been genetically modified to be resistant to glyphosate are used to grow crops.

Glyphosate is the highest selling active ingredient in Canada according to the 2011 sales data,[2] which unfortunately remains the most recent data available, at over 25 million kilograms.

Glyphosate is contained in no fewer than 169 registered pest control products in Canada, including in 34 domestic class products.

2) Glyphosate Products Threaten Unacceptable Risks to Human Health

In this section of our comments, we set out two overarching areas of concern with the PMRA's Proposed Glyphosate Decision. First, we address our concern that the PMRA has been improperly dismissive of the assessment of the World Health Organization's conclusion that glyphosate is probably carcinogenic to humans – there is no justification for the PMRA's dismissive approach to the work of international experts. Second, we address the PMRA's failure to comply with various requirements under s. 19(2)(b) of the *PCPA.*

a) IARC classification

In March 2015, 17 experts from 11 countries met under the International Agency for Research on Cancer ("IARC") of the World Health Organization ("WHO"). WHO is a specialized public health agency of the United Nations. The IARC working group's task was to assess the carcinogenicity of five organophosphate pesticides, including glyphosate.

After these international experts' exhaustive evaluation of the science, IARC classified glyphosate as 'probably carcinogenic to humans'.[3]

To our surprise and concern, the Proposed Glyphosate Decision is singularly dismissive of the IARC classification of glyphosate, albeit with very little rationale supporting its rejection of IARC's assessment. First, the Proposed Glyphosate Decision notes that "a hazard classification is not a health risk assessment". Second, it states that "the level of human exposure, which determines the actual risk, was

[2] Health Canada. Pest Control Products Sales Report for 2011.
[3]Kathryn Z Guyton, Dana Loomis, Yann Grosse, Fatiha El Ghissassi, Lamia Benbrahim-Tallaa, Neela Guha, Chiara Scoccianti, Heidi Mattock, Kurt Straif, on behalf of the International Agency for Research on Cancer Monograph Working Group, IARC, Lyon, France. *Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate*. March 20, 2015.
< http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)70134-8/abstract> Accessed on June 2, 2015.

not taken into account by WHO (IARC)."[4] Finally, it claims that pesticides are registered for use in Canada only if the level of exposure to Canadians does not cause any harmful effects including cancer.

No further justification is offered by the PMRA in the Proposed Glyphosate Decision for rejecting IARC's classification of glyphosate as probably carcinogenic, other than noting that it reviewed a number of published epidemiological studies including the subset considered by IARC. PMRA dismisses these studies relied on by IARC stating that, "the majority lacked adequate characterization of glyphosate exposure, rendering them of limited use for supplementing the hazard assessment."[5]

However, the PMRA provides no references or further reasons supporting its critique of IARC's work. Without any explanation as to why PMRA staff believe that IARC's international experts' reliance on published studies was inappropriate, it is difficult to comment on PMRA's superficial, summary review of the studies relied on by IARC.

The studies referenced by IARC with respect to the glyphosate classification in the assessment summary titled "Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate" are the four published, peer-reviewed studies listed below:

- De Roos AJ, Zahm SH, Cantor KP, et al. Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men. *Occup Environ Med* 2003; 60: E11.

- WHO/FAO. Glyphosate. Pesticides residues in food 2004 Joint FAO/WHO Meeting on Pesticides Residues. Part II Toxicological. IPCS WHO 2004; 95–162. http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/.

- Bolognesi C, Carrasquilla G, Volpi S, Solomon KR, Marshall EJ. Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: association to occupational exposure to glyphosate. *J Toxicol Environ Health A* 2009; 72: 986–97.

- McDuffie HH, Pahwa P, McLaughlin JR, et al. Non-Hodgkin's lymphoma and specific pesticide exposures in men: cross-Canada study of pesticides and health. *Cancer Epidemiol Biomarkers Prev* 2001; **10:** 1155–63.

By stark contrast, the studies referenced by PMRA staff for the toxicological hazard assessment[6] are largely unpublished, non-peer reviewed studies submitted by the registrants themselves. Of the 118 studies that the Proposed Glyphosate Decision lists as considered for the toxicological hazard

[4] Proposed Glyphosate Decision, p.3
[5] Proposed Glyphosate Decision, p. 15
[6]References B. Studies Considered for the Toxicological Hazard Assessment. p. 256

assessment, only seven of them were published studies not provided by the registrants. Of those seven studies, only one is a study that IARC's international experts saw fit to rely upon.[7]

While IARC describes its assessment that glyphosate is "probably carcinogenic to humans" as a hazard classification, it is factually inaccurate to represent the IARC evaluation as not taking into account human exposure. The studies relied on by IARC all examine glyphosate exposure in great detail – including the cross-Canada study of over 2000 men. The three published studies that IARC relies on are briefly summarized in **Appendix A** to this letter**.**

Thus, overall, the Proposed Glyphosate Decision fails to provide any valid reason for rejecting the scientific assessment of IARC's international experts.

Recommendation: Taking into account the IARC assessment resulting in the classification of glyphosate as a 'probably carcinogenic to humans', and considering and giving appropriate weight to the findings and the studies relied on by IARC, conduct a proper precautionary review of the cancer risk to Canadians from glyphosate. Based on that review, end the registration of glyphosate products that present a carcinogenic risk to humans.

b) PCPA s. 19(2)(b) requirements in relation to health risks

Paragraph 19(2)(b) of the *PCPA* sets out a number of specific factors to be evaluated, in any re-evaluation, with respect to health risks.

i) Aggregate Exposure

Pursuant to s. 19(2)(b)(i), the Agency must evaluate the "aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational sources, including drinking water and use in and around homes and school".

The residential aggregate exposure and risk assessment is presented in Section 3.5 of the Proposed Glyphosate Decision.

Toxicological endpoint of concern appears insufficiently protective

As PMRA guidance material explains, an aggregate exposure assessment begins with identification of a toxicological endpoint of concern for the particular substance.[8]

The toxicological endpoint selected by PMRA for the non- occupational aggregate exposure risk assessment is an effect on salivary glands. For that endpoint, PMRA relied on a 26 month chronic toxicity and carcinogenicity study on rats with a no observed adverse effect level (NOAEL) of 32/34 mg/kg bw/day. This is the same study used to determine the acceptable daily intake (ADI) of 0.3 mg/kg bw/day of glyphosate in Section 3.2.3 of the Proposed Glyphosate Decision, which is further examined below in the section under the application of the PCPA factor.

[7] WHO/FAO. Glyphosate. Pesticides residues in food 2004 Joint FAO/WHO Meeting on Pesticides Residues. Part II Toxicological. IPCS WHO 2004; 95–162.
[8] Science Policy Note SPN 2003-04. July 28, 2003. General Principles for Performing Aggregate Exposure and Risk Assessments. p.12

The Proposed Glyphosate Decision does not explain why this particular endpoint was chosen. Nor does the Proposed Glyphosate Decision claim that the effect on salivary glands is the most sensitive endpoint. The USEPA Integrated Risk Information System (IRIS) notes a critical effect study with a NOAEL of 10 mg/kg/day,[9] which is a notably lower NOAEL than the saliva study used by the PMRA as a toxicological endpoint in the aggregate assessment. Overall, the PMRA's chosen endpoint does not appear to be sufficiently precautionary or scientifically well-founded.

Recommendation: Review the toxicological and epidemiological literature and determine whether there is a more sensitive endpoint of concern that can and should be used in the aggregate assessment. Among potential alternatives, choose the endpoint which best exemplifies a precautionary, scientifically well-founded approach. If the PMRA decides not to use a more sensitive endpoint of concern, it should explain in detail why more sensitive endpoints were rejected.

The PMRA selected the same toxicological endpoint for the intermediate and long term occupational and bystander exposure risk assessment. Like with the aggregate exposure assessment, the Proposed Glyphosate Decision does not explain why this particular endpoint was chosen. Given that IARC's classification of glyphosate as a 'probably carcinogenic to humans' was based largely on epidemiological studies linking occupational and bystander exposure to non-Hodgkin's lymphoma, we question whether the PMRA's assessment is based on the most sensitive endpoint and takes into account IARC's classification.

Recommendation: Review the toxicological and epidemiological literature, especially the literature relied on by IARC, and determine whether there is a more sensitive endpoint of concern that can and should be used in the occupation and bystander assessment. Among potential alternatives, choose the endpoint which best exemplifies a precautionary, scientifically well-founded approach. If the PMRA decides not to use a more sensitive endpoint, it should explain in detail why more sensitive endpoints were rejected, and whether the selected endpoint and resulting NOAEL will protect against the risk of developing non-Hodgkin's lymphoma or other cancers from occupational and bystander exposures.

Aggregate risk assessment assumptions are flawed

The aggregate exposure is the total exposure to glyphosate that may occur from food, drinking water, residential and other non-occupational sources, and from all known exposure routes (oral, dermal and inhalation). In a risk assessment, PMRA compares the aggregate exposure assessment to the chosen toxicological endpoint and a margin of exposure (MOE) is calculated. The MOE is the ratio between the estimated exposure and the no observed adverse effect level (NOAEL). A minimum MOE of 100 is desired to account for inter and intra species variation with respect to toxicological effects.[10] In the case of threshold effects, an additional factor may be used called the 'PCPA factor' which is discussed further below.

The PMRA guidance material also explains that aggregate exposure scenarios should correspond to the exposure durations deemed to be of significance in light of the toxicity data available for the pesticide.[11]

[9]Increased incidence of renal tubular dilation in F3b offspring. Available at <http://www.epa.gov/iris/subst/0057.htm> Accessed on June 8, 2015

[10] Science Policy Note SPN 2003-04, *supra* note 8, p.34

[11] *Ibid*., p. 12,

At pages 27-29, the Proposed Glyphosate Decision examines the following three aggregate exposure scenarios:

- Inhalation and dermal exposure to homeowners (adults) applying glyphosate to lawns/turf + postapplication dermal exposure (adults) performing activities in treated areas + chronic dietary (food and drinking water).

- Postapplication dermal exposure (youth and children [6 to < 11 years old]) from performing postapplication activities in treated lawns/turf + chronic dietary (food and drinking water).

- Postapplication dermal exposure (children 1 to < 2 years old) + incidental oral exposure (hand-to-mouth) from performing postapplication activities in treated lawns/turf + chronic dietary (food and drinking water).

All three aggregate exposure scenarios include multiple routes of exposure. In addition, all three aggregate exposure scenarios initially assumed a glyphosate application rate of two applications with a seven day interval. At that application rate, the calculated MOEs for the adult and the youth/children (6 to <11 years old) scenarios reached the target MOE of 100, but the MOE for children (1 to < 2 years old) for the postapplication + incidental oral exposure + chronic dietary scenario did not reach the target of 100. Unfortunately, the Proposed Glyphosate Decision does not provide the actual MOE analysis and results for this scenario in the report (see Appendix IX Table 1).

In response to this finding, PMRA simply *changed* the aggregate assessment to one application of glyphosate with a seven-day time-weighted turf transferable residue average for the entire aggregate assessment for all populations. The average residues of glyphosate were calculated over a seven-day span, rather than assuming exposure to residues immediately after application. The PMRA rationalizes its change to the aggregate assessment by stating that, "the two applications (with an seven days interval) at the maximum application rate is a highly conservative exposure assumption, as it is unlikely that children would be exposed to turf residues of the highest rate, at the lowest interval of application immediately after application.[12]"

While two applications seven days apart may not be likely, it is entirely possible and permitted, according to PMRA's own proposed changes to the product labels.[13] Thus, it would be a more appropriate and precautionary aggregate exposure risk assessment to instead assume exposures immediately after application at the maximum application rate and frequency.

Rather than simply changing the aggregate risk assessment assumptions upon discovering that aggregate exposures exceed levels the PMRA considers safe for human health, a precautionary approach would be to propose changes to the labels of glyphosate products to further restrict the application rate and frequency of use.

[12] Proposed Glyphosate Decision, p. 28

[13] The Agency is proposing to change the product label to require a seven day interval between applications. At present there is no such requirement for domestic class products. (see Appendix IIb page 69)

Recommendation: Use the highest application rate and frequency of glyphosate use to assess the aggregate exposures, and, if safety margins (MOE) are not met, propose meaningful and wide-ranging use restrictions to increase human health protection.

ii) Cumulative Effects

Pursuant to s. 19(2)(b)(i), the PMRA must consider, in relation to human health effects, "…cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity".

The Proposed Glyphosate Decision declines to assess any cumulative effects. It makes no attempt to address the statutory requirement in s. 19(2)(b)(1) to consider cumulative effects of glyphosate pest control products and other pest control products that have a common mechanism of toxicity.

The PMRA fails to assess the cumulative effects in three distinct ways

First, the PMRA does not assess the cumulative effects of the many registered pest control products, listed in Appendix 1 of the Proposed Glyphosate Decision, that all contain glyphosate. Clearly these 169 products have common mechanisms of toxicity. The PMRA is under a duty to assess their cumulative effects.

Second, the PMRA does not assess the cumulative effects of those pest control products containing glyphosate that *also* contain a second active ingredient such as 2,4 D[14] , dicamba[15] or glufosinate ammonium.[16] Nor does it assess the cumulative effects of the various surfactants – such as polyethoxylated tallow amines, and metabolites and transformation products of those surfactants – used in glyphosate products. If glyphosate products containing other active ingredients or other potentially toxic substances that have a common mechanism of toxicity, cumulative effects must be assessed.

Third, and most concerning, the Proposed Glyphosate Decision does not assess if these 169 pest control products have common mechanisms of toxicity with other pest control products in Canada. The PMRA's failure to identify common mechanisms of toxicity does not mean that common mechanisms of toxicity do not exist. Indeed, to rely on a lack of full scientific certainty about the nature or extent of common mechanisms of toxicity, as a justification for not assessing cumulative effects at this point in time, would be inconsistent with the precautionary principle. The lack of any consideration of cumulative effects is especially concerning given the increased risk of Non-Hodgkin's Lymphoma with exposure to increased number of pesticides documented in the study cited by IARC in their classification of glyphosate discussed above.[17]

Recommendation: Conduct an assessment of the cumulative effects of the glyphosate pest control product and other pest control products that have a common mechanism of toxicity as required.

[14] Product Registration numbers 19536, 25898
[15] Product Registration numbers 20423, 21572, 29552
[16] Product Registration numbers 25604, 25795, 25918
[17] De Roos AJ, Zahm SH, Cantor KP, et al. Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men. Occup Environ Med 2003; 60: E11.

iii) Application of the PCPA Factor

Under s. 19(2)(b)(iii), the PMRA must apply an additional margin of safety if a product is used around homes or schools in case of threshold health effects, to take into account the completeness of the data with respect to the exposure of and toxicity to infants and children, and potential prenatal and postnatal toxicity. Specifically, s.19(2)(b)(iii) directs the PMRA to:

> *"in the case of a threshold effect, if the product is used in or around homes or schools, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph (ii) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children, unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate".*

PMRA guidance material explains this provision as requiring a presumptive application of the 10-fold factor (also referred to as the PCPA factor), aimed at the protection of infants and children. In other words, the onus is on the PMRA to provide a reliable scientific rationale in those cases where the 10-fold PCPA factor is reduced.[18]

This guideline also explains that different PCPA factors can be used for different exposure scenarios. Different exposure scenarios for infants and children are likely here, as many glyphosate domestic class products can be used around homes and schools.[19]

As stated above at page 5, the PMRA relied on a 26 month chronic toxicity rat study as the basis for the ADI. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intra-species variability were applied resulting in an ADI of 0.3 mg/kg bw/day of glyphosate. However, the PMRA reduces the PCPA factor to one-fold. The reason that PMRA provides for this reduction to a one-fold factor is that 'there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children.'

This does not appear to be a defensible conclusion. There does appear to be some evidence of sensitivity of infants and children to glyphosate. Indeed, this is evident from studies discussed in the Proposed Glyphosate Decision. Two of three studies cited found decreased body weight in rat pups was observed at non-maternally toxic dose,[20] although the Proposed Glyphosate Decision claims that these reductions in body weight were considered marginal. Glyphosate was also found to impair male offspring differential development in a study reported in the journal Archives of Toxicology.[21] Here, a

[18] Science Policy Note. SPN2008-01. The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides. p.11

[19] There are 34 domestic class glyphosate products. The labels of domestic class products reviewed at random (ex. Registration nos. 22627, 22627, 22627,27506, 28469, 28576) did not indicate any restrictions on use around homes or schools.

[20] Proposed Glyphosate Decision, p. 14

[21] Marco Aurelio Romano , Renata Marino Romano , Luciana Dalazen Santos ,Patricia Wisniewski , Daniele Antonelo Campos , Paula Bargi de Souza , Priscila Viau , Maria Martha Bernardi, Maria Tereza Nunes, Claudio Alvarenga de Oliveira. Glyphosate impairs male offspring reproductive development by disrupting gonadotropin expression. Arch Toxicol (2012) 86 663:673 <http://link.springer.com/article/10.1007/s00204-011-0788-9#page-2>

precautionary approach requires that the PMRA apply the additional 10-fold PCPA factor as additional safety factor given that glyphosate is used in and around schools and homes, and given that there is some evidence of threshold effects differentially impacting infants and children.

The PMRA reduced the PCPA factor to one fold in its assessment of all toxicological points of departure used in human health risk assessment, with only one exception. The PMRA reduced the PCPA factor from 10-fold to three-fold in determining an acute reference dose for females aged 13 to 49, based on an increased incidence of fetal cardiovascular malformations.[22]

In addition, the Proposed Glyphosate Decision does not address the possibility of endocrine disruption. Instead, with respect to risks to terrestrial organisms, it states that endocrine disruption effects will be considered when the results of a US EPA screening program become available.[23] Endocrine disruption in wildlife is likely also an indication of endocrine disruption in humans given that hormones and their signally pathways are often quite similar across species.[24] The failure to assess endocrine disruption represents an uncertainty with respect to the toxicity of glyphosate to infants and children, given endocrine disrupting chemicals can interact with the thyroid system impacting brain development during pregnancy and after birth. In addition, exposure to endocrine disrupting chemicals has been linked to increasing rates of neurobehavioral disorders like including dyslexia, mental retardation, ADHD and autism.[25]

Recommendation: the PMRA should apply a PCPA factor of 10-fold as an additional margin of safety with respect to human health threshold effects, as required under the *PCPA*.

3) Glyphosate Products Threaten Unacceptable Impacts to Monarch Butterfly Populations

The Monarch butterfly is currently listed as a species of Special Concern under the *Species at Risk Act,* SC 2002, c 29 ("*SARA*").

However, since the Monarchs were first listed under the *SARA* and then re-assessed scientifically in 2010, the population has continued to decline precipitously. Annual counts of the size of the overwintering Monarch population in Mexico indicate that the population has declined by 65% between 1999 and 2010.[26] Another study has estimated that the Monarch production has declined 81% between 1999 and 2010.[27]

Presently, there is good reason to believe that Monarch Butterflies are more appropriately classified Threatened or Endangered. As a result, and given s. 24 of *SARA,* COSEWIC is currently conducting an

[22] Appendix III. Table III.2. Page 91.
[23] Proposed Glyphosate Decision, p. 37
[24] WHO. 2012. State of the Science Endocrine Disruption Chemical. Summary for Decision Makers. p.4. Available at < http://www.who.int/ceh/publications/endocrine/en/> accessed on June 11, 2015
[25] *Ibid.* p. 9.
[26] Brower, L.P., Taylor, O.R., Williams, E.H., Slayback, D.A., Zubieta,R.R. & Ramirez, M.I. (2011b) Decline of monarch butterflies overwintering in Mexico: is the migratory phenomenon at risk? Insect Conservation and Diversity. doi: 10.1111/j.1752-4598.2011.00142.x.
[27] Hartzler, R.G. (2010) Reduction in common milkweed (Asclepias syriaca) occurrence in Iowa cropland from 1999 to 2009. Crop Protection, 29, 1542–1544.

updated status assessment to review the classification of this species, to assess if its scientific status is Threatened or Endangered. The COSEWIC status report, under s. 21 of *SARA,* is intended to be completed later this year.

Despite the precarious situation in which Monarch butterflies find themselves, in Canada and indeed throughout North America, the Proposed Glyphosate Decision makes no mention of the risk to Monarchs' survival that is threatened by glyphosate products. Put simply, the extensive use of glyphosate in North America is killing and destroying milkweed that Monarchs need to survive and recover. Peer-reviewed scientific studies have shown the effects on Monarch butterflies of milkweed loss due to herbicide use.[28]

Monarch butterflies in Eastern North America have a remarkable multi-generational life cycle that includes wintering in central Mexico. In the spring, adults that have overwintered migrate north and reproduce in Texas and other US states; the offspring of these butterflies then move north into the United States and southern Canada, producing additional generations. Thus the adverse effects of glyphosate on Monarchs and their habitats are worsened by its extensive use not just in Canada, but also in the United States.[29]

Habitat loss in the Mexican overwintering area is considered to be a significant threat.[30] Recent studies, however, indicate that the loss of the larval host plant milkweed in the breeding grounds due to the use of glyphosate herbicide in glyphosate-resistant crops is an additional, significant threat.[28] Monarch larvae feed primarily on milkweed plants – which grow around crops such as corn and soybeans.

Glyphosate-resistant crops were first introduced in the United States in soybeans in 1996.[31] Adoption was very rapid in soybean and has grown significantly in corn. The largest land areas of glyphosate-resistant crops are occupied by soybean and corn. Given the dominance of glyphosate-resistant crops and widespread use of glyphosate herbicide, scientists have predicted the virtual disappearance of milkweeds from the corn and soybean production region.[28] A study in the Midwestern states, the dominant corn and soybean growing region in North America, found an estimated overall reduction in milkweed resources of 72% in corn and soybean fields from 1999 to 2009.[32] It is very likely that a similar reduction has occurred throughout the broad region where corn and soybeans are predominantly grown in North America – including regions of Ontario and Quebec.

Inexplicably, the Proposed Glyphosate Decision does not consider effects of widespread glyphosate product use on milkweed population and availability in Canada, and the resulting impacts on Monarch butterfly populations. To protect non-target vascular plants, at the very minimum, spray buffer zones are required on glyphosate product labels. However, such a condition would not protect milkweed as

[28] Pleasants, J. M., & Oberhauser, K. S. (2013). Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population. *Insect Conservation and Diversity*, *6*(2), 135-144.
[29] Pleasants, J. M., & Oberhauser, K. S. (2013). Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population. *Insect Conservation and Diversity*, *6*(2), 135-144.
[30] COSEWIC Assessment
[31] Dill, G. M., CaJacob, C. A., & Padgette, S. R. (2008). Glyphosate-resistant crops: adoption, use and future considerations. *Pest Management Science*, *64*(4), 326-331.
[32] Hartzler, R.G. (2010) Reduction in common milkweed (Asclepias syriaca) occurrence in Iowa cropland from 1999 to 2009. Crop Protection, 29, 1542–1544.

milkweed is often considered a *target* plant. Indeed, despite the fact that it is habitat for the Monarchs, it is identified as a "perennial weed' on many glyphosate product labels.[33]

Recommendation*:* Conduct a precautionary review of environmental effects of continued registration of pest control products containing glyphosate on Monarch butterflies and on their milkweed habitat, and propose meaningful and wide-ranging use restrictions.

Thank you for considering the foregoing summary of our concerns. Our organizations would welcome a further opportunity to comment on a Revised Proposed Glyphosate Decision.

Yours sincerely,

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Ecojustice Canada

Kathleen Cooper, Senior Researcher
Canadian Environmental Law Association

Lisa Gue, Senior Researcher and Analyst
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for the Environment

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[33] For example, Roundup original, Vision Silviculture Herbicide, Roundup Dry, Touchdown 480, Glyphos Soluble

APPENDIX A

Summaries of three published studies relied on by IARC

McDuffie HH, Pahwa P, McLaughlin JR, et al. Non-Hodgkin's lymphoma and specific pesticide exposures in men: cross-Canada study of pesticides and health. Cancer Epidemiol Biomarkers Prev 2001; 10: 1155–63.

This study found a dose response relationship between Non-Hodgkin's Lymphoma (NHL) and increased glyphosate exposure. The study collected pesticide exposure histories from over 500 NHL cases and 1500 control subjects across Canada. The information was collected through a questionnaire by trained interviewers overseen by study coordinators, and was statistically analyzed. Contrary to PMRA's claim in the proposed re-evaluation, this study is focused on assessing exposure. It is also important to note that given this study was conducted on subjects in Canada it is likely that the glyphosate use was according to label requirements and therefore reflective of typical exposures in Canada from the use of registered glyphosate pest control products.

De Roos AJ, Zahm SH, Cantor KP, et al. Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men. Occup Environ Med 2003; 60: E11.

This study was similar to the one above and found that the use of several individual pesticides was associated with increased NHL incidents among famers including glyphosate, and suggested a positive trend of risk with exposure to increasing numbers of pesticides used indicating the importance of assessing multiple exposures.

IARC references both of these studies as a case control studies that found an increased risk of NHL from exposure to glyphosate after adjustment for other pesticides.

Bolognesi C, Carrasquilla G, Volpi S, Solomon KR, Marshall EJ. Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: association to occupational exposure to glyphosate. J Toxicol Environ Health A 2009; 72: 986–97.

This paper found an increase in the frequency of micronuclei in blood, an indicator of chromosomal damage, in populations after exposure to aerial spraying of glyphosate compared to control populations where glyphosate was not sprayed.