Submission to the Standing Committee on Climate Change and Environmental Stewardship on the Federal Registration of Glyphosate

Submission to the Standing Committee on Climate Change and Environmental Stewardship on the Federal Registration of Glyphosate

From: Mary Lou McDonald of Safe Food Matters Inc. May 25, 2021

Introduction

My name is Mary Lou McDonald, and I am a lawyer, and the president of Safe Food Matters Inc. I have been a lawyer for 27 years. Safe Food Matters is a Canadian non-profit, working on policy to protect human health and the environment from pesticides, crop inputs and food production technologies that may be harmful.

Safe Food Matters has taken Health Canada to Federal Court over its 2017 reassessment of glyphosate, which is the federal basis for the re-registration of glyphosate use in Canada until the 2030s at least. The 2017 reassessment was the first time glyphosate had been looked at for 45 years: since it was registered in Canada in 1976. Our court case is ongoing, with an appeal to be heard at the Federal Court of Appeal likely this year.

In this presentation, I intend to speak to the risk assessment that the Pest Management Regulatory Agency ("**PMRA**") conducted on glyphosate, on behalf of Health Canada, which formed the basis for the re-registration decision. This assessment was set out in two documents, known as the Preliminary Re-Evaluation Decision (PRVD 2015-01) and the Final Re-Evaluation Decision (RVD 2017-01). (I will reference these as "**PRVD**" and "**RVD**", respectively.)

I will point out some major problems with PMRA's risk assessment. I will speak from the perspective of what the law requires, and what Health Canada's own policy documents require, so that we can get an understanding of what both the letter and the spirit of the law require.

Why do this? Because many provincial and local authorities point to this assessment (and the 2017 re-registration decision that was based on it) of Health Canada to say that "glyphosate is safe".

An Assessment of Risks, Not Safety

Let me say at the outset that glyphosate is not "safe". The question isn't even about "safety". PMRA does not ask itself whether glyphosate is safe; instead it asks itself whether the **risks** associated with glyphosate are "acceptable". Note how the idea of "acceptable risk" presumes that are risks associated with glyphosate. This idea that there are inherent risks with pesticides runs throughout the Pest Control Products Act (the "**Act**").

Need "Reasonable Certainty of No Harm" to Protect Health and the Environment

In order for the risks to be "acceptable", the Act (s. 1(2)) requires there be a "**reasonable certainty that no harm to human health, future generations or the environment will result** from exposure to or use of the product", taking into account directions on the labels.

Another fundamental idea in the Act is that PMRA is supposed to ensure that humans and the environment are protected from these risks. The "value" of glyphosate, whether social or economic or crop improvement, or whatever, is secondary. Value takes a back seat to the priority of protecting

humans and the environment from the risks of pesticides. It is only once PMRA is sure that the risks are acceptable can they even consider the value of glyphosate.

Executive Summary

In this presentation, the key points to be made are the following:

- Risk = hazard x exposure
- The scope of PMRAs risk assessments on health and the environment were lacking
    - PMRA did not examine the whole pest control product, look at cumulative effects or correctly apply safety and uncertainty factors
- PMRA's human health hazard assessment dismissed effects on the human gut and next generations
- PMRA's human health exposure assessment was flawed:
    - Dietary exposure was based on irrelevant and outdated data
    - Occupational exposure evidence dismissed
    - PMRA did not protect vulnerable populations
- PMRA's cancer assessment was flawed:
    - No exposure assessment
    - Problems with the hazard assessment
    - Undue reliance on one study
    - Missapplication of the *Weight of Evidence* Approach
- PMRA's assessments were based on tainted science and connections
- PMRA's environmental risk assessment has risks of concern that cannot be mitigated by labels
- PMRA worked with EPA on the environmental risk assessment, but EPA is set to revise its work
- There is no international consensus on glyphosate, despite what PMRA suggests
- Many countries are banning and restricting glyphosate
- A particular note on forests: that current uses are not what PMRA approved

Proper Scope of Assessment

In terms of the scope of the risk assessment, I would like to point out what is called for, and then show how PMRA did meet these requirements. First, the Act asks not just for an assessment of the ingredient itself, the so called "active ingredient" that is known to kill the pest. Legislators know that other chemicals are added to the products to add to the effect of glyphosate, so they ask for an assessment of the entire glyphosate product, known as a "pest control product", which includes formulants and contaminants. This makes sense, because people and the environment are exposed to the whole product, not just one ingredient.

The definition of a "pest control product" is:

> *(a) a product, an organism or a substance, ….. that consists of its active ingredient, **formulants and contaminants**, and that is …. used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects;*

PMRA Did Not Examine the Whole Pest Control Product

PMRA did not perform an assessment on the whole pest control product. It made reference to only one other ingredient in glyphosate products: the surfactant polyethoxylated tallow amines ("**POEA**"). A surfactant is added to the formulation to make the active ingredient "stick" better. PMRA indicated that a majority of registered glyphosate end-use products contain POEA (PRVD p. 10), but it did not perform a risk assessment on POEA. It referenced a 2010 human health assessment of a subfamily of POEA conducted by the US Environmental Protection Agency ("**EPA"**), and said (PRVD p. 29) that this can be used for the assessment of POEA in Canada. PMRA did not provide this human health assessment.

PMRA also did not speak to any other constituent chemicals to the glyphosate product. These other chemicals are not reported or even known, because the registrants consider the formulations to be proprietary data; so there is no way PMRA can state that the glyphosate products will not result in harm. PMRA indicated that as of September 16, 2016, there were 185 products containing glyphosate (RVD Appendix II), all containing chemicals that are not known or assessed. The number of products is likely higher now. Science is showing that chemicals added to glyphosate products may even in some cases be more toxic than the active ingredient.

PMRA Did Not Look at Cumulative Effects

The second point concerns cumulative effects. Lawmakers realized that in the real world, a pest control product can interact with other chemicals, so they asked for assessment of the "**cumulative effects**" of pest control products together with other chemicals that have a common mechanism of toxicity on the plants. (Section 7(b)).

PMRA did not conduct a cumulative effects assessment. In RVD 2017-01 (p. 27) PMRA stated that glyphosate acid does not belong to a pesticide group that requires assessment of cumulative effects because glyphosate acid does not appear to share a common mode of toxicity with other pesticides.

PMRA Did Not Correctly Apply Safety or Uncertainty Factors

Third, the Act requires that certain "safety and uncertainty factors" be put in place and applied to the findings of tests, to deal with certain uncertainties or vulnerable populations. Emphasis is placed on the safety of infants and children. In relation to the evaluation of health risks, the Act in section 19(2) requires that PMRA apply margins of safety to take into account the sensitivities of major identifiable subgroups (including infants and children). It also requires, if the product is used in or around homes or schools, that the margin of safety be **ten times greater** (the "**Home or School Factor**") than that for the major identifiable subgroups, unless PMRA has determined "on the basis of reliable scientific data", that a different margin of safety would be appropriate.

Glyphosate is used in or around homes and schools, so the ten times Home or School Factor should have applied. PMRA, however, reduced this factor from 10 to 1 (and from 10 to 3 in one scenario) (PRVD p.17), indicating that there were no uncertainties with respect to potential toxicity to infants and children. However, the fact that PMRA did not consider there to be uncertainties is not "reliable scientific data" that justifies reducing the legally mandated Home or School Factor of 10.

It can be seen from the above that the scope of the risk assessment by PMRA fell short of what the Act requires.

Understanding Risk Assessments

Two Risk Assessments

So who makes the call on whether the risks associated with glyphosate are acceptable? The PMRA of course. How did they do it? They conduct two risk assessments – one on the risks to human health from the use of glyphosate, and one on the risks to the environment.

Risk = Hazard x Exposure

"Risk" is generally understood in terms of the formula: "Risk = hazard x exposure". "Hazard" is about how harmful the product is, and "exposure" is about how much of the product humans or the environment are exposed to in real life. PMRA says: "A pesticide with low toxicity and high exposure could pose a similar risk as a pesticide with high toxicity and low exposure".[1]

The rest of this presentation shows how PMRA did not conduct proper risk assessments of human health (including cancer) or environmental risks. Examples will be taken from how PMRA dealt with "hazards" and "exposure" in both the health and the environmental risk assessments.

Human Health: Hazard Assessment

A hazard assessment describes how the pesticide works and how harmful it is. Health Canada provides a good explanation of this in its document, the *Decision-Making Framework for Identifying, Assessing and Managing Health Risks* (the "**Framework**"). A hazard assessment asks "is it harmful?" and "how harmful is it?". Most of the science in hazard assessment comes from lab work or from studies of disease in populations (epidemiological studies)**.**

What has become obvious in recent years is that PMRA in its assessment did not understand how glyphosate harms humans. Three of its major failings are: PMRA did not consider that glyphosate affects the human gut; that it has effects on future generations; and that it can cause or contribute to cancer. PMRA's view on the first two points is set out below, and the cancer discussion occurs later.

Human Microbiome

In RVD2017, PMRA provided its response to comments submitted on the preliminary re-evaluation decision, PRVD 2015. Comments were submitted indicating reports show that glyphosate impacts human intestinal microbiome and that this can harm humans. PMRA dismissed the reports by essentially saying that this could not be the case (RVD p. 30), and that studies in the lab that show this are not good enough:

> *"Glyphosate targets an amino acid synthesis pathway in plants that is shared by certain types of bacteria, but not humans. There is very little scientific evidence to support the claim that glyphosate has any direct impact on human gut microflora, or has any subsequent health effect. Several reports postulate that environmental chemicals may potentially lead to changes in normal gut microbiota. However, information to date is based on in vitro studies, with in vivo evidence being very limited and inconclusive.*

[1] PMRA, Science Policy Note (SPN 2003-03) *Assessing Exposure from Pesticides in Food A User's Guide* spn2003-03-eng.pdf (canada.ca)

However, glyphosate does affect the human gut. It affects the overall bacteria constitution of the microbiome. Glyphosate is an antibiotic that kills beneficial bacteria, and when it is ingested it disrupts the balance in the gut. The effect on the microbiome was shown with "in vivo" (animal studies) evidence in a May, 2018 article, which found that exposures to commonly used glyphosate products, at doses considered safe, are capable of modifying the gut microbiota in early development, particularly before puberty. Thus the in vivo studies desired by PMRA exist.

Generational Effect

PMRA said it looked at three, two-generation toxicity studies in rats to assess reproductive toxicity (PRVD p. 14). It noted reduced body weight of pups, but thought this was marginal, and said that it expected harmful effects on the parents (even though the effects on parents were not examined), therefore "no evidence of sensitivity of the young was observed in these reproduction toxicity studies".

However, the effects of glyphosate are showing up in later generations. A December 2020 study indicates that it caused problems in later generations, including prostate disease, kidney disease, obesity, and presence of multiple diseases. Earlier studies have similar findings.

Human Health: Exposure Assessment

The Framework indicates that in an exposure assessment, the question is "what levels are humans exposed to?" PMRA looks at the pathways by which people can be exposed: through eating and drinking pesticides in their food and water (dietary exposure and drinking water exposure), by workers breathing it in or getting it on their skin when it is being sprayed (occupational exposure) and by members of the general population (including youth and children) being exposed after spraying (non-occupational exposure).

Dietary Exposure Based on Old, Irrelevant Data

With respect to the dietary exposure assessment of PMRA, there are a couple of big problems. First, PMRA does not look at the **current levels of glyphosate** in our food. The last and only time the Canadian Food Inspection Agency ("**CFIA**") even looked at the levels of glyphosate in our food was in 2015.

Second, PMRA also does not get any data on the quantity of contaminated foods Canadians are currently eating. None. Instead, it takes data from household surveys, from ALMOST 30 YEARS AGO (1994-1996 and 1998) from a typical household IN THE UNITED STATES (PRVD p. 18):

> *"Acute and chronic exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model – Food Commodity Intake DatabaseTM (DEEM-FCIDTM, Version 2.14), which incorporates* ***consumption data from the United States*** *Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII)* ***from 1994 to 1996 and 1998****."*

This means that what Americans ate in the mid 1990s is the basis for our Canadian dietary risk assessment on glypshosate. It cannot be said with any legitimacy that this data is a valid basis from which to assess what Canadians are currently eating: a different people, eating different types of foods, looked at almost 30 years ago.

Occupational Exposure Evidence Dismissed, Although Big Wins in US Civil Court Cases

With respect to occupational exposure, the problem is that glyphosate is being strongly linked to cancers in people who spray it for a living in both the US and Canada; in particular, it is being strongly associated with non-Hodgkin lymphoma in epidemiological (human population) studies. PMRA dismissed the association, stating that it needs evidence of causation (RVD p. 23):

> *"Without a causal relationship, epidemiology data cannot be used to establish references doses or occupational endpoints".*

Three US civil lawsuits against Monsanto (now Bayer) are cases in point. These cases were won (and continue to be won) on the basis that Round-up (which contains glyphosate) caused or was a substantial factor in causing cancer in those who spray it.

The first major US case was of Dewayne Lee Johnson, a groundskeeper who sprayed Roundup around schools and developed non-Hodgkin lymphoma. In 2018, the California jury found Roundup had caused his cancer, and Bayer (successor to Monsanto) paid Johnson $20.5 million in December, 2020.

The second US case was of Edwin Hardeman, who in 2019 was awarded USD 80 million because Roundup was a "substantial factor" in causing his non-Hodgkin lymphoma. Hardeman had used it on his properties to control weeds and poison oak.

The third US case was of Pilliod v. Monsanto, which concerned a couple who had sprayed Round up around their yard for years. On May 13, 2019, jurors returned a verdict awarding Alva and Alberta Pilliod and **unheard of amount of** $2 billion in punitive damages and $55 million in compensatory damages, finding Roundup caused the Pilliods' non-Hodgkin lymphoma. The "Judges Order Reducing the Pilliod Damages" lowered this amount, mainly because in fact such a large amount was unheard of; there was an "unconstitutionally large ratio" between punitive and compensatory damages (p. 22).

Lawsuits are now in the works in Canada, following the US example. A $500 million class action lawsuit was launched in late 2019, alleging that Roundup can cause cancer, including non-Hodgkin lymphoma. Many of the cases concern farmers who have developed the disease.

Exposure to Children and Vulnerable Populations

As discussed above, PMRA did not apply the Home or School Factor required Act when it came to assessing the risks of spraying on homes or schools. In addition, PMRA changed the exposure assessment for spraying lawns and turf by changing the base exposure scenario, from assuming glyphosate is sprayed two times to being sprayed one time, and then taking the average concentration of glyphosate over the 7 days following.

The reason for the change is that without it, the exposure of children 1 to 2 years old (who crawl in grass) did not meet the targeted level of the ratio of toxicity/exposure; called the margin of exposure or MOE. PMRA stated (PRVD 2015 p. 28):

> *"When conducting the aggregate exposure scenario, two applications (with a seven-day interval) at the highest rate were assumed. All calculated MOEs [margins of exposure] reached the target MOE* ***except for children (1 to < 2 years old****) for the postapplication + incidental oral exposure + chronic dietary scenario.* ***Therefore, dietary and non-dietary refinements were required****….*

> *Therefore, a refinement using **one application** of glyphosate along with a **seven-day time-weighted TTR average** was used (the average residues were calculated over a seven-day span) for the entire aggregate assessment for all populations."*

PMRA justified the change by indicating it is unlikely that children would be subject to the higher exposure scenario, stating "it is unlikely that children would be exposed to turf residues of the highest rate, at the lowest interval of application immediately after application." However, common sense says that if a child under 2 is taken to the park or crawls in grass daily or almost daily, the child would likely be exposed to the higher exposure scenario.

PMRA is not protecting vulnerable populations, including children and infants, in its health risk assessments, as mandated by section 19(2) of the Act.

Human Health: Cancer Assessment

No Quantitative Risk (Exposure) Assessment for Cancer

In Science Policy Note SPN 2000-01 "Technical Paper: A Decision Framework for risk assessment and risk management in the Pest Management Regulatory Agency" (the "**Technical Paper**"), PMRA explains that it applies two different approaches for assessing the acceptability of risks from pesticides: "a margin of safety approach for "threshold effects" and a **quantitative risk assessment** for non-threshold effects, such as cancer" (p. 6).

The quantitative risk assessment is further described in PMRA Science Policy Note *SPN2003-03 Assessing Exposure from Pesticides in Food, A User's Guide*, which presents detailed acute, chronic and cancer-risk assessment procedures for PMRA (PRVD p. 18). The "quantitative risk assessment" for cancer entails the use of "sophisticated statistical models to **estimate** potential cancer risks at the **lower levels of exposure seen in humans**". It requires an exposure estimate.

However, PMRA did **NOT** estimate potential cancer risks from the levels of glyphosate seen in humans. It **did not conduct the exposure assessment**. It only conducted a hazard, or toxicology assessment.

(Moreover, PMRA does not even have the tools to calculate certain types of cancer risk. It explains in SPN 2003-03 (at 10) that cancer risk can be liner or non-linear. Linear cancer risk is expressed as a probability, whereas nonlinear cancer risks is calculated using the MOE approach where a **margin of exposure** (MOE) would be calculated. It admits (at 10):

> *"For nonlinear cancer risk assessment, the PMRA has not yet determined an appropriate target MOE. It is currently developing criteria to make that judgement"*.)

PMRA at p. 15 of PRVD provides one paragraph on its cancer assessment, under the heading "Toxicology Summary". It states that the risk of cancer is unlikely based on its understanding of the evidence:

> *"[T]he **overall weight of evidence** indicates that glyphosate is unlikely to pose a cancer risk. This is consistent with all other pesticide regulatory authorities world-wide…".*

The evidence that PMRA said it considered in making its "overall weight of evidence" statement was a "large body of information on glyphosate that had strengths and limitations, which included multiple

short and long term (lifetime) animal toxicity studies, numerous in vivo and in vitro genotoxicity assays, as well as the large body of epidemiological information".

The studies referenced by it (animal toxicity, in vivo and in vitro genotoxicity assays, and epidemiology) are all part of and discussed as part of the Toxicology section of PRVD. The failure to perform an exposure assessment is a significant failing, and it is the same problem that, ironically, PMRA finds with the finding of the International Agency on Cancer (IARC) that glyphosate is "probably carcinogenic to humans" (PRVD p.3): [2]

> "The World Health Organization's (WHO) International Agency for Research on Cancer (IARC) recently assigned a hazard classification for glyphosate as "probably carcinogenic to humans". It is important to note that a hazard classification is not a health risk assessment. **The level of human exposure**, which determines the actual risk, was not taken into account by WHO (IARC)".

Problems with the Hazard Assessment for Cancer

Further, there are problems with PMRA's hazard assessment. The approach for the hazard assessment (the potential for a chemical to cause cancer) is set out in PMRA's *Technical Paper*. The approach requires looking at evidence from cancer studies on 2 species, and evidence from in vitro (in the test tube) and in vivo (animal studies) genotoxicity studies. (Genotoxicity is damage to the genetic information within a cell causing mutations, which may lead to cancer). The approach then requires looking at the mechanisms by which the cancer could be caused.

PMRA in its *Technical Paper* (p.7) says this is the approach of the International Agency on Cancer (IARC), and endorses the approach. The International Agency on Cancer, as describe in the book *The Monsanto Papers* [3] is "part of the World Health Organization (WHO) and is solely devoted to studying cancer research and encouraging international projects aimed at preventing cancer worldwide. IARC, based in Lyon, France, doesn't do new research; the group's scientists analyze existing public research about substances that people are widely exposed to and for which cancer concerns may exist. PMRA states:

> "The assessment of a chemical's potential to cause cancer requires a different kind of assessment and expression of risk. Cancer risk assessment for pesticides is based on evidence from cancer studies in at least two species, usually the rat and the mouse, together with evidence from in vitro and in vivo genotoxicity studies. The cancer studies are evaluated on the basis of the number and type of lesions elicited in test animals. They are typically carried out at dose levels that are much higher than expected human exposures. These studies are in many cases complemented with studies that shed light on the mechanism by which the pesticide causes the carcinogenic effect. The outcome of the animal studies together with mechanistic considerations are used in a weight-of-evidence approach to decide if a pesticide is likely to pose a cancer risk to humans. **This type of approach is used by the International Agency for Research on Cancer in identifying agents that may pose a cancer risk to humans**."

In the studies PMRA looked at, and evidence presented to PMRA from IARC, the requirements of the *Technical Paper* were met, but PMRA dismissed the evidence. There was toxicity evidence of cancer in at least two species, as will be explained below. There was also evidence of toxicity from the in vitro and in

[2] IARC probably carcinogenic

[3] Carey Gillam, *The Monsanto Papers*, Island Press, 2021, p. 26

vivo genotoxicity studies PMRA examined. The mechanism by which glyphosate causes cancer was also evident. However, PMRA stated in a table with respect to "Cancer Risk" that the level of concern was low "due to the benign nature of tumours observed at the limit dose and lack of oncogenicity in other studies" (PRVD p.92 Table III.2). (Oncogenicity is the capability of inducing tumour formation).

Three studies in the PMRA database showed the requisite statistically significant evidence of cancer: one genotoxicity study in hamster cells and two chronic rat studies. This was pointed out to PMRA in a notice of objection filed to the glyphosate decision, and the point was also made that cancer can occur in a non dose-related manner (as pointed out above in the *Technical Paper*), but PMRA dismissed the studies and the objection.

In addition, although PMRA says that these is a lack of oncogenicity in other studies, the results of its own Chronic Toxicity/ Oncogenicity Studies stated "Equivocal evidence of oncogenicity", meaning the data showed more than one interpretation.

PMRA was also aware of studies showing the mechanisms by which glyphosate can cause cancer, but dismissed them because the studies provided by the registrant did not exhibit such mechanisms (RVD p. 20). These studies, and others that relate to findings of cancer in rodent studies, were described in a 2015 Open Letter (the "**Open Letter**") and a 2016 article that pointed out the differences between the hazard cancer evaluation of IARC and that of other regulatory authorities. PMRA did not consider the studies.

Undue Reliance on the Agricultural Health Study

Epidemiology is the branch of medicine which studies the incidence and distribution of disease in a population. With respect to epidemiology, PMRA looked at epidemiological studies as part of the hazard analysis of cancer; with respect to exposure, it mentioned only **one** epidemiological study (in its section on "Epidemiology" in PRVD (p.15)). This was the Agricultural Health Study, and there are serious concerns with this study.

PMRA said the Agricultural Health Study ("**AHS**") examined the relationship between glyphosate exposure and the incidence of multiple mylema (a cancer), but that there were "confounding factors" to the association that rendered the suggestion inconclusive and that "chance occurrence could not be ruled out". PMRA stated the "study investigators" said more follow up is needed on the association between cancer and glyphosate. PMRA again referenced the AHS in response to a comment in RVD2017 (p. 22), and indicated that "evidence for an exposure-trend by duration or intensity of pesticide use was not observed during the relatively short period (enrollment in the study was 1993-1997 to end of 2001) of follow-up (PMRA#:2391583)", and that no correlation was observed in a follow-up analysis of male participants.

This reliance of PMRA on the "Agricultural Health Study" is problematic. In the US civil case of Dewayne Lee Johnson, described above, Court records showed that a major flaw with the study was that the follow ups should be accorded no weight, for two reasons. First, because they did not account for the increased use of glyphosate in 20 years after the data was collected, and also the researchers had lost contact with many of the original subjects and so couldn't perform a proper follow up, which skewed the findings:

"[T]he AHS researchers had lost contact with tens of thousands of original study subjects and so had added in data based on what they inferred those subjects might have told them had they been able to re-connect to follow-up. The practice, known as imputation, was common in epidemiology, but the AHS imputation had been so skewed that it had introduced a 17 percent error rate, hopelessly invalidating the risk ratios".[4]

What is also problematic is the disregard of many epidemiological studies that **did** show correlations between glyphosate and cancer, for which causality between glyphosate and cancer was credible (see the Open Letter). PMRA again pointed to the problem of lack of exposure data in order to dismiss these studies. It stated that it had viewed the epidemiological information considered by the WHO (IARC) in their summary report on glyphosate, but that "the majority **lacked adequate characterization of glyphosate exposure**, rendering them of limited use for supplementing the hazard assessment" (PRVD p.15).

Misapplication of Weight of Evidence of Approach

PMRA in its cancer assessment dismissed all of this evidence or cherry-picked the evidence it liked, saying it was using the "weight of evidence" approach ("**WOE Approach**"). However, PMRA did not properly apply the WOE approach, which is NOT supposed to be about dismissing or cherry-picking evidence, but about looking at a study in the context of other studies (forming a "line of evidence") to see if they point to a certain conclusion.

"Examining the Weight of Evidence" "involves determining and examining the weight of the scientific evidence, in a qualitative way, order to determine **whether there is support for the conclusions about risk."** In this instance, it would be about weighing a study to see if it supports a line of evidence pointing to the conclusion that glyphosate can cause cancer.

The cherry-picking and dismissal can be seen from the following explanations of PMRA:

- Cherry-picking studies on glyphosate alone, and dismissing studies on the full product, like Round-up:
    - "[S]tudies conducted with glyphosate alone were considered more relevant in characterizing its inherent toxicity **than were studies on the formulated products reported in the scientific literature**, as the latter contained a variety of other constituents that, in most cases, were not identified." (RVD p. 18)
    - "Although it is argued that formulated glyphosate products are more representative of 'real life' conditions, it is important to keep in mind that many different products (pesticide and non-pesticide) share many of these same constituents. In order to fully characterize a pesticide active ingredient, it is necessary to understand its inherent toxicity, which can only be characterized in the absence of these other constituents."

- Cherry-picking the unpublished, confidential studies of the corporate registrant (saying they complied with testing practices of the OECD) and dismissing peer-reviewed published studies:
    - "In addition, studies that complied with internationally accepted test guidelines were considered by the PMRA to be more relevant and reliable than published studies

[4] Carey Gillam, *The Monsanto Papers*, Island Press, 2021, p. 273.

conducted with methodologies not recognized by regulatory agencies or organizations, such as the OECD." (RVD p. 19)

- Dismissing findings of IARC of the "evidence on cancer from at least two species", as required by PMRA itself in the *Technical Paper*, apparently because the findings occurred at low dose or the limit dose, or the tumours were not repeated in other studies:
    - "Pancreatic islet cell adenomas were noted in male rats in two of the rat studies. However, these findings were not dose-related and/or occurred at the low dose only." (RVD p. 21)
    - "The IARC also reported a statistically significant positive trend for hepatocellular adenomas in male rats only (with no evidence of pre-neoplastic lesions or progression to carcinomas), and a statistically significant positive trend for thyroid C-cell adenomas in female rats only. **None of these tumours were reproduced in other chronic studies in rats.**" (RVD p. 21)
    - "For the two mouse studies, the IARC identified a positive trend for renal tubule adenomas and carcinomas in male mice in one study, and a positive trend for hemangiosarcoma in males in the other study. **However, these tumours were not reproduced in other mouse studies**, which used similar and higher doses (1000-4000 mg/kg bw/day)."

- Cherry-picking the Greim review on rodent studies:
    - "Since the publication of PRVD2015-01, a review by Greim et al. (201513) of 14 long-term glyphosate toxicity/carcinogenicity studies in rodents included four additional studies in rats and three additional studies in mice, which were negative for carcinogenicity". (RVD p. 21)

- Dismissing its own findings of evidence of cancer because of the dose or because in PMRA's view other data makes the finding unlikely:
    - "PRVD2015-01 reported a marginal increase in the incidence of ovarian tubulostromal hyperplasia and adenomas in mice. However, since adenomas were **observed at the limit dose of testing**, they were not considered relevant for human health risk assessment." (RVD p. 21)
    - "Furthermore, additional historical control data submitted during the PRVD comment period indicated that the incidence of ovarian adenomas was actually within the historical control range for the conducting laboratory, which **increased the likelihood** that these tumours were not treatment-related." (RVD p. 21)

- Dismissing positive evidence of genotoxicity, by stating it is "likely associated with surfactants" present in the whole product itself, not to the active ingredient alone.
    - "It is important to characterize the relationship of genotoxic results in the context of observed cytotoxicity. Positive results at very high or toxic dose levels indicate that the genotoxic effects are due to cytotoxicity rather than direct DNA-acting properties of glyphosate formulated products. ….. The observed cytotoxicity is **likely associated with surfactants that are present in many formulated products**. For example,

polyethoxylated tallow amines (POEAs), which are typical surfactant components of **many glyphosate products**, were shown to produce cytotoxic effects such as perturbation/disruption of the mitochondrial membrane in cultured mammalian cells (Levine et al. 2007,11 Kier and Kirkland 201312). (RVD p. 20)

- Cherry picking evidence from Kier and Kirkland (2013):
    - "A number of negative genotoxicity studies were reported by Kier and Kirkland (2013), but not considered by the IARC." (RVD p. 20)

- Dismissing evidence of the mechanisms presented by IARC, because one study presented by the registrant Monsanto didn't show it, nor did the toxicity database supplied by the registrant:
    - "However, no evidence of glyphosate-induced immunosuppression was observed in a **registrant-supplied guideline immunotoxicity** study reviewed by the PMRA. In addition, no other studies in the **extensive toxicity database** suggested a concern for immunotoxicity, inflammation or oxidative stress." (RVD p. 20)

Tainted Science and Connections

It will be seen from the above that the "cherry-picked" science that PMRA preferred was the confidential toxicology studies supplied by the registrant, the Greim rodent study review, and the Kier and Kirkland (2013) review. It has come to light that the last two were ghostwritten or co-written by Monsanto.

Ecojustice Investigation

Ecojustice in November 2018 investigated the studies forming part of the so-called "Monsanto Papers", and reported in a backgrounder to the article it published on the issue as follows:

> "*Ecojustice legal counsel and scientist conducted a review of the materials contained in the Monsanto Papers. This review reveals that the PMRA in its re-evaluation of glyphosate relied on some studies and papers in which Monsanto's role is uncredited or unclear. For instance:*
>
> - *The manuscript for the genotoxicity review study by **Kier and Kirkland, 2013 was co-written by Monsanto scientist Dr. Saltmiras, although his name was not included on the study**. See here on pages MONGLY02145925 and MONGLY02145918. The PMRA refers to this study on footnote 12 on page 20 of the re-evaluation decision in addressing comments about the IARC assessment.*
>
> - *Dr. Saltmiras of Monsanto indicates he **ghostwrote the cancer review paper Greim et al. 2015** that the PMRA relied on for assessing carcinogenicity studies in animals on footnote 13 on page 21 of the re-evaluation decision. Dr. Saltmiras is shown as the second author. See here.*
>
> - *Internal Monsanto email suggests ghost writing sections of a paper and having experts edit and sign, and recalls that that was how Monsanto handled Williams Kroes and Munro, 2000. See here MONGLY00977267. The Williams Kroes and Munro, 2000 study is listed in the reference list of the glyphosate re-evaluation decision. [Listed at RVD p. 96]*

- *The manuscript for the report that led to the Williams GM et al. 2016 study titled, "A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment" was reviewed and edited by a Monsanto scientist even though it was presented as "independent." See here, here, here, and here. The PMRA relied on this study in their decision regarding the re-evaluation. [Listed at RVD p. 96]*

- *The Williams AL et al. 2012 study titled, "Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure: A Critical Analysis" was edited and redrafted by a Monsanto scientist, but the Monsanto scientist's name was removed from the manuscript before publication. See here. [Listed at RVD p. 96]*

New Brunswick Connections

The Ecojustice backgrounder (pps. 2,3) also speaks to possible Monsanto connections to New Brunswick:

> *"According to a July 2016 email Monsanto Canada "reached out to Keith Solomon and Len Ritter, both retired Professor Emeritus faculty from the University of Guelph. Len did confirm that he has been contracted by the province of New Brunswick and the Ontario Public Health Agency, among others, to assist with their review of the IARC findings on glyphosate." Later that month New Brunswick Public Health released a report on glyphosate downplaying the IARC classification calling it a "hazard assessment" and stating that the scientific consensus regarding the risks posed by glyphosate is still "elusive" pointing to the ongoing assessments in Canada, US, and Europe." See* here.

The dictates of scientific integrity and evidence-based policy making require that the science underlying risk assessments be objective and independent and free from manipulation and outside influence. The US is currently taking steps to safeguard science. The White House recently announced a Scientific Integrity Task Force further to President Joe Biden's January, 2021 Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. Task force goals include "prevent(ing)the suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results."

Such integrity should be brought to bear in relation to the tainted science described above, and also in relation to a recent finding. It has come to light that the US Agency for Toxic Substances and Disease Registry, a respected, independent institution, has issued a final report regarding the risk of Non-Hodgkin lymphoma in pesticide applicators, and the final report has findings that are not supported by the draft. The draft included a study that showed statistically significant evidence that glyphosate causes non-Hodgkin lymphoma, but the in the final report the study was downplayed as not showing such evidence.

Environmental Risk Assessment: Risks of Concern Exist

At paragraph 8.2 of PRVD, PRMA provided its summary on environmental risk (p. 48). It stated that glyphosate is toxic to estuarine/marine fish. It stated there was a risk of concern for terrestrial plants (plants on the ground). It was that glyphosate poses a risk to freshwater algae, and if the product contains POEA it poses a risk to freshwater invertebrates, freshwater plants and marine/estuarine invertebrates.

It is clear from the above there is a reasonable certainty of harm to the environment from the use of glyphosate. This is not a product for which the risks to the environment can be considered "acceptable".

PMRA's solution for these problems should have been to discontinue the registration for glyphosate use in the environment. But instead, PMRA amended the labels for spraying glyphosate to put in place "spray buffer zones".

Labels Do Not Protect the Environment

These amended labels on spray buffer zones do not protect the environment. They do not provide any buffer zones whatsoever for the terrestrial environment. They require spraying at times when the winds are neither calm or gusty. They include other non-helpful, unprotective statements such as the following:

> "Buffer zones for the protection of terrestrial habitats are not required for forestry uses or for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases".
>
> "DO NOT apply during periods of dead calm or when winds are gusty"
>
> "Glyphosate is very toxic to non-target plants".
>
> "Do not use in areas where adverse impact on domestic water or aquatic species is likely" (Dow label p.44)

PMRA is making some significant, and wrong, assumptions in thinking that label amendments will protect the environment. It assumes the labels will be followed, and that they will be enforced. However the statistics show that labels concerning the use sites and locations are not followed correctly.

The Regulatory Operations and Enforcement branch of PMRA issued an annual report for the 2017-2018 fiscal year (and has not published one since). It performed inspections of operators of pest control products, and **found 65% of them were not in compliance** at the time of inspection (p. 19). Using the product contrary to the label was the main violation, with over 40% of the violations relating to incorrect use sites or locations:

> *"The use of pest control products **contrary to label directions** continues to be the primary violation reported, **particularly related to incorrect use sites or locations** (39), pest not included on the label (30)…. Possessions of unregistered (never registered or expired) products was also noted in 20 instances."*

Another problem with PMRA's approach is it ignores the fact that the toxicity of glyphosate to environmental species has an impact on the entire ecosystem that houses those species, not just the species themselves. PMRA does not look at this; it does not conduct an ecosystem or a cumulative effects assessment. This is the case, even though it knows that "contact with a treated area and ingestion of vegetation treated with a product containing glyphosate" were activities that led to deaths of animals (PRVD p. 30).

By way of example, glyphosate is allowed to be sprayed on forests and no spray buffer zones are required to protection terrestrial plants, such as berries. Glyphosate accumulates and concentrates in

the berries of the plants because it is a systemic chemical that translocates to the growing fruits. The animals that eat these berries are consuming high levels of glyphosate in their diets, and harmed. The animals that rely on the berries die. A recent B.C. study shows that glyphosate stays in the tissues of forest plants for a decade or more. Allowing glyphosate to be sprayed no forests is in no way protective of the environment.

EPA Set to Revise its Environmental Risk Assessment

The United States Environmental Protection Authority is the American equivalent of the Canadian PMRA. The EPA and the PMRA collaborated on the re-evaluation of glyphosate (RVD2017 p. 9). The document REV2010-02 Re-evaluation Work Plan for Glyphosate outlined the work sharing between the two organizations, and stated:

> *"The PMRA will be working cooperatively with the USEPA on the re-evaluation of glyphosate. The overall Canadian re-evaluation timelines will be closely aligned with those of the US EPA".* (p.1)

The collaboration is evident from the number of references to the EPA approach and science in PRVD 2015 and RVD 2017.

In May, 2021, the EPA switched directions. It asked the federal court for a chance to review and possibly revise its assessment of glyphosate, as it pertains to value and ecological risks (ie. the environment). The Court documents (at 9) speak to various factors, including a previous court decision that "concluded that EPA had failed to properly acknowledge the risks and impacts of spray drift" associated with another pesticide, dicamba. It would appear that EPA may well alter the findings of its ecological (environmental) risk assessment.

No International Consensus

Regulatory Authorities are Restricting/Banning Glyphosate Across the World

PMRA often makes statements to the effect that its decisions on glyphosate are consistent with the decisions of other regulatory authorities around the world. In RVD (pp.8,9) it stated: "Glyphosate is currently acceptable for use in other OECD countries, include the United States, Australia and the European Union"; and "Currently, no pesticide regulatory authority, including Health Canada, considers glyphosate to be a carcinogenic risk of concern to humans".

Since 2017, however, as many as 42 countries, states, regions and cities have taken steps to either ban or restrict the use of glyphosate. The list includes: Austria, states in Australia, France (an OECD country that will ban by 2021 with limited exceptions), Germany (an OECD country that will ban by 2024), states in India, Italy, Mexico (an OECD country that will ban by 2024), the Netherlands, cities in New Zealand, regions in Spain and Sweden, among others.

A Note on Forests

Trees Are Not a Pest

The Act defines a "Pest" as something that is "injurious, noxious or troublesome":

> ***pest*** *means an animal, a plant or other organism that is injurious, noxious or troublesome, whether directly or indirectly, and an injurious, noxious or troublesome condition or organic function of an animal, a plant or other organism.*

Species of trees and growth that exist in the natural environment alongside trees that have value in forestry cannot seriously be considered as meeting the definition of injurious, noxious or troublesome, particularly against the background purposes of the Act. The preamable and sections of the Act are clear that biological diversity is of value, that the environment needs to be protected from the risks of pesticides, and that "the development and use of alternative, non-toxic, ecological pest control approaches" is to be encouraged.

Based on this understanding, the use of glyphosate to kill competing growth and trees is not permitted under the four corners of the Act.

RVD Approval Assumes Use is Once Every 50 to 80 Years

PMRA, in providing response to comments in RVD, indicates that glyphosate exposure to forest is extremely low. The reason is because glyphosate is used to prepare the site for reforestation after trees are harvested; and this occurs only once every 50 to 80 years. PMRA's statements are as follows:

> *Moreover, glyphosate products containing POEA are used in forestry to prepare the site for reforestation which requires that the products be applied only once per silviculture cycle; typically equating to once every 50 to 80 years. As such, the potential for amphibian exposure to glyphosate products is limited in silviculture. Based on these findings, the PMRA concluded that there were no reasonable grounds to believe that the environmental risk to amphibians in small ephemeral forest wetlands from the spraying of glyphosate products was unacceptable. (RVD p. 50)*
>
> *As noted in response to comment 2.2.5, glyphosate is used for forest site preparation and plant release (conifers and deciduous trees) after trees are harvest. This use is expected to occur once every 50-80 years. As such, glyphosate exposure to forest is extremely low*. (RVD p. 57)

Based on the above, the use of glyphosate to kill competing growth and trees during the silverculture cycle was not assessed for risk in the environmental risk assessment, and glyphosate should be used on forests only once every 50 to 80 years.

Value of Forestry Use Secondary to Environmental Risk

As stated at the beginning of this presentation, the Act is clear that the value proposition for a pesticide is secondary to the primary purpose of protection human health and the environment from unacceptable risks associated with pesticide use. This means that regardless of how helpful and efficient glyphosate is in forestry, its use should not be allowed unless there is a reasonable certainty of no harm to the forests arising from the use. There is no such reasonable certainty.

Conclusion

In summary, the risks assessments performed by PMRA that underlie the current registration of glyphosate are not adequate to protect human health, the environment or future generations. The assessments do not prove "safety"; rather they show the application of problematic scientific approaches and evidence (and ignoring of evidence) to arrive at very questionable findings of "acceptable risk". It is hoped that the risk assessments will be seen for what they are, and that undue reliance will not be placed on them.