Court File No. T-956-21

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.
and PREVENT CANCER NOW

Applicants

and

ATTORNEY GENERAL OF CANADA
and MINISTER OF HEALTH

Respondents

Court File No. T-1412-21

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.
and PREVENT CANCER NOW

Applicants

and

ATTORNEY GENERAL OF CANADA
and MINISTER OF HEALTH

Respondents

AFFIDAVIT OF MARY LOU McDONALD
(Affirmed November 3, 2021)

I, Mary Lou McDonald, of the Township of Gilmour, in the Province of Ontario, AFFIRM AS FOLLOWS:

1. I am the President of one of the applicants in this proceeding, Safe Food Matters Inc. ("**SFM**"). As such I have personal knowledge of the matters set out in this affidavit. Where I do not have such knowledge I have set out the source of my information and belief and I believe the information to be true.

2. SFM is a Canadian non-profit corporation, founded in 2016. SFM has worked to protect the health of the environment and humans by contributing to and advocating for the development of government policies that limit the use of harmful pest control products and crop production technologies. SFM has previously participated in and been engaged on consultations conducted by Health Canada and the Pest Management Regulatory Agency ("**PMRA**") on proposed policies, and has submitted objections to the registration of potentially harmful pesticides.

Background to my involvement in this matter

3. Prior to my involvement with SFM, I participated in numerous regulatory processes on harmful substances, including:

   - Acting as a Canadian public interest participant to the Basel, Rotterdam and Stockholm Conventions on Persistent Organic Pollutants January 2014 to June 2019;
   - Commenting on Canada's Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports in 2013;
   - Petitioning the federal Auditor General Commissioner of the Environment and Sustainable Development requesting a ban of Decabromodiphenyl Ether (DecaBDE) and a change to the *Bioaccumulation Regulations* in 2008.

4. SFM comments on a wide range of pesticide issues with an emphasis on food safety and monitors and follows Health Canada approval processes on pest control products such as Glyphosate, Organophosphates, Genetically Modified Foods, and participates in these processes at appropriate times.

5. Since starting up in 2016, SFM has engaged in campaigns on genetically modified foods, and is extensively engaged in the regulation of Glyphosate.

6. In addition to these topics SFM provided submissions to the New Brunswick Standing Committee on Climate Change and Environmental Stewardship on the PMRA's risk assessment process for Glyphosate and the defects in that process. Attached as **Exhibit "A**" is a copy of that submission.

7. SFM performs advocacy work on government policies in order to limit the use of harmful pest control products and crop production technologies. SFM is currently engaged in litigation with Health Canada on its refusal to grant SFM's request in its notice of objection under the *Pest Control Products Act* for a review panel to review the registration of the pest control product Glyphosate. One of the objections made by SFM related to the setting of maximum residue limits ("**MRLs**") of Glyphosate for certain crops. The respondents did not challenge the standing of SFM in that proceeding.

8. SFM has commented publicly on the PMRA's persistent delays. For example, in June 2021, SFM provided a comment on the delays in the Chlorpyrifos re-evaluation on its website. This is attached as **Exhibit "B"**. In October 2020, SFM commented on the delays in the re-evaluation which turned the 15 year review cycle into a 39 year review cycle. This is attached as **Exhibit "C"**.

9. SFM has also participated in other related regulatory processes such as commenting on genetically modified food issues arising from Health Canada's proposed new guidance on Novel Foods in 2021. SFM was recently engaged in a campaign opposing PMRA's proposal to increase MRLs in food for Glyphosate, and the proposal has been paused.

<u>The Environmental Re-evaluation Decision and Notice of Objection</u>

10. On December 10, 2020, the PRMA released decision RVD2020-14, "Chlorpyrifos and Its Associated End-use Products (Environment)" (the "**Final Re-evaluation Decision**"). This "final" decision completed the re-

evaluation of the environmental risks of Chlorpyrifos. It did not include a decision on the human health re-evaluation of Chlorpyrifos, which had been ongoing since 1999. In the Final Re-evaluation Decision the PMRA continued certain categories of uses of Chlorpyrifos, and discontinued other uses based on environmental risk. This is described in more detail at paras 23-24 of the Affidavit of Margaret Sears.

11. On February 8, 2021, SFM, Prevent Cancer Now ("**PCN**") and eight other organizations submitted to Minister of Health, the Honourable Patricia Hadju, a Notice of Objection to the Final Re-evaluation Decision pursuant to section 35 of the *Pest Control Products Act*. This Notice of Objection is attached to this affidavit as **Exhibit "D"**.

12. This Notice of Objection dealt with the environmental portion of the re-evaluation and is described in paragraphs 25-33 of the Affidavit of Margaret Sears.

13. A second Notice of Objection was submitted on February 8, 2021, by Bill Jeffery, Executive Director and General Counsel for the Centre for Health Science and Law. In the second Notice of Objection, Mr. Jeffery addressed the PMRA's delay in developing and releasing the Chlorpyrifos human health risk assessment. This Notice of Objection is attached to this affidavit as **Exhibit "E"**.

<u>The PMRA Data Call Decision and final decision on the Human Health re-evaluation</u>

14. After the final decision in the environmental portion of the Chlorpyrifos re-evaluation in December 2020, the issued a "Data Call-In" for the Chlorpyrifos active ingredient. This data call is included as **Exhibit H** to the affidavit of Margaret Sears and is described in paras 36-38 of that Affidavit. The Data Call-In was issued only days after the two notices of objection were filed as described above.

15. On May 13, 2021, the PMRA published a Re-evaluation Note REV2021-02, "Update on the Re-evaluation of Chlorpyrifos", under which the PMRA

cancelled all remaining Chlorpyrifos uses and products as a consequence of the registrants' failure to satisfy the data requirements and ordered the existing stocks of all Chlorpyrifos products to be phased out on a three-year timeline. This decision is attached as **Exhibit "F"**.

16. The decision to cancel all remaining uses of Chlorpyrifos, while allowing a three-year phase out period, did not provide any rationale for the three year delay in ending sale and use. For example, the decision does not state that the risk of three more years of use of Chlorpyrifos would be acceptable or in accordance with the risk prevention objectives of the *Pest Control Products Act* or explain if or whether the PMRA concluded this. The decision does not provide any reason or explanation for either the scope of the delay or the reason why it was deemed appropriate.

17. After the decision SFM commented on the decision on the SFM website and in an article in the National Observer. While SFM was pleased with the cancellation decision, it was disappointed with the failure to conduct a health re-evaluation after more than two decades of delay and the long and unjustified phase-out period in light of what is known about the potentially serious health risks of Chlorpyrifos. This is reflected in SFM's public comments.

18. On May 21, 2021, I received a response to our Notice of Objection from the PMRA, proposing that the objection be closed due to the cancellation decision announced in REV2021-02. This is attached as **Exhibit "G"**. No other reasons were provided for not establishing the panel.

19. Following the PMRA's decision in May 2021 to cancel Chlorpyrifos registrations with a three-year phase-out for existing stocks, SFM and Prevent Cancer Now commenced this judicial review application.

20. I was informed by my counsel on this judicial review application, and believe it to be true, that we were served with the Certified Tribunal Record ("**CTR**") for this application on August 17, 2021. Counsel has advised me that the CTR

contains a record of decision and briefing note for an MRL Trackers' Meeting on April 19, 2021.

21. I did not know that the PMRA made a new decision regarding MRLs in April 2021 until I was advised by my counsel about the contents of the CTR. There is no documentation of this decision in the Public Registry for the Chlorpyrifos re-evaluation. I am not aware of any other public notice of this decision.

22. I make this affidavit in support of the within judicial review application and for no improper or other purpose.

AFFIRMED REMOTELY by Mary Lou McDonald stated as being located at the Township of Gilmour, in the Province of Ontario, before me at the Municipality of Prince Edward County in the Province of Ontario, on November 3, 2021, in accordance with *O. Reg 431/20, Administering Oath or Declaration Remotely*.

Commissioner for Taking Affidavits
(or as may be)

Charlotte Ireland, LSO # P10772

MARY LOU MCDONALD

This is **Exhibit "A"** referred to in the affidavit of **Mary Lou McDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 3rd day of November, 2021.

Commissioner for Taking Affidavits
(or as may be)

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.

This is **Exhibit "B"** referred to in the affidavit of **Mary Lou McDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 3rd day of November, 2021.

Commissioner for Taking Affidavits
(or as may be)

safe • food MATTERS

DELAY, DELAY … BY THE PMRA

2021-06-14 SFM Chlorpyrifos Leave a comment

PMRA delays deciding on chlorpyrifos, then delays ban for 3 years. *Safe Food Matters* and *Prevent Cancer Now* bring Court challenge.

A Health Canada agency is delaying the cancellation of the dangerous chemical, thereby exposing Canadians to continued harm. Chlorpyrifos is a hazardous neurotoxic pesticide, known for

SEE POSTS ON:

- Chlorpyrifos
- Glyphosate
- GM
- Other

ABOUT US/ CONTACT

Safe Food Matters Inc. is a Canadian non-profit corporation, founded in 2016, dedicated to safe food and a safe environment. We work to improve regulatory

permanently damaging the brains of developing children.

The Pest Management Regulatory Agency (**PMRA**) didn't cancel the chemical back in 2007 when it learned of the dangerous health risks, and it issued a cancellation statement only in May, 2021 – which allows continued "phase-out" use for another 3 years. The sales of this pesticide are consistently in the top 10 in Canada, so the quantities are significant.

Between 2007 and 2017, the US Environmental Protection Agency (**EPA**) published several human health risk assessments, linking chlorpyrifos to adverse neurodevelopmental effects. The PMRA said it would follow the EPA documents "in detail" and reassess them in the Canadian context. But it did not. It sat on the sidelines while the US story played itself out, allowing the dangerous chemical to stay registered in Canada for years.

In 2016, the EPA issued its human health evaluation and was set to ban the chemical, until Trump took office. Trump's EPA Administrator Scott Pruitt reversed course in March 2017 and allowed for continued use. Dow Chemical, an original manufacturer of chlorpyrifos, contributed USD 1 Million to Trump's inauguration committee.

One of the first statements made by President Biden was to take a hard look at this chemical, and on April 29, 2021 the 9th Circuit Court of Appeals forced the cancellation decision in the US courts,

policies to better protect human health and the environment.

Our current topics are glyphosate, chlorpyrifos, and GM (genetically modified/edited products). To see our collections on a topic, click on the topic link in a post or on the sidebar.

We are going to court over Health Canada's 2017 re-registration of glyphosate. Please help with legal costs by donating through direct transfer to safefoodmatters@gmail.com or

tearing a strip off the EPA for its delay, saying "the EPA's time is now up". Europe banned chlorpyrifos in 2019 because there was no safe level, allowing a three-month "grace period" to clear stocks.

The PMRA last assessed health risks in 2003 ("*Proposed Acceptability for Continued Registration*"), and its December 10, 2020 environmental risk decision allowed for continued use to spray mosquitos, elm and mountain pine trees, and indoors and around residential structures. In the December document, the PMRA said it would be updating its human health risk assessment. Two notices of objection to the 2020 environmental assessment were filed on February 8, 2021.

Two days later, on February 10, 2021, the PMRA issued a "data call" to companies who had registered the product (requesting data that was decades old). The companies did not respond, and the PMRA used this technicality to issue its cancellation statement: one month after the US court decision. The PMRA does not intend to respond to the two objections, one filed by a collection of 10 groups, and the second filed by the Centre for Health, Science and Law.

The cancellation statement isn't really a cancellation, though. It's a cancellation "in a few years". It allows for continued use for all chlorpyrifos uses/ products until December 10, 2023. No explanation or legal justification for the thee-year delay following the December, 2020 environmental decision is provided. No

through our GoFundMe link. Every little bit helps! Thanks.

Email: safefoodmatters@gmail.com

Website: safefoodmatters.org

Facebook: https://www.facebook.com/safefoodmatters/

Twitter: https://twitter.com/safefoodmatt

Instagram: https://www.instagram.com/safefoodmatters/?hl=en

GoFundMe: gf.me/u/y4qsvc

acknowledgement of the risks of chlorpyrifos is mentioned.

Safe Food Matters Inc. and Prevent Cancer Now think a cancellation should be a cancellation "now" or "in a few months" (like in Europe): not "in a few of years". They think the *Pest Control Products Act* supports their position. The primary purpose of the Act is to *prevent* unacceptable risks to Canadians and the environment; not to *protract* unacceptable risks for long "phase-out" periods.

They filed a Notice of Application in Federal Court on June 14, 2021, asking for a review of the cancellation decision. Ecojustice, a national environmental law charity, is helping provide a legal team of lawyers to assist on the case.

Safe Food Matters Inc. is a Canadian non-profit corporation, engaged in policy issues on pesticides and crop production technologies that harm Canadians and the environment. It is the only group taking Health Canada to Court over the continued registration of glyphosate, the main ingredient in Roundup. It would like to see increased resources for the regulator so it can perform adequate and timely risk assessments independent of corporate influence and reliance on the US process. Contact: Mary Lou McDonald, LL.B., SafeFoodMatters@gmail.com

Prevent Cancer Now is a Canadian science-based non-profit group that aims to stop cancer before it starts, including by eliminating adverse exposures that

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This is **Exhibit "C"** referred to in the affidavit of **Mary Lou McDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 3rd day of November, 2021.

Commissioner for Taking Affidavits
(or as may be)

SAFE FOOD MATTERS, BUT NOT TO HEALTH CANADA ?

2020-10-21 SFM Glyphosate 2 comments

BUT NOT TO HEALTH CANADA ?

Safe food matters to you and me, but does it matter to Health Canada? We aren't convinced. Why not? We have been in a David vs. Goliath battle with them since 2017 regarding their regulatory approach to safe food, and have two basic observations. First, in our view, Health Canada hasn't followed the intent or the letter of the law. Second, the conduct of the regulator has been problematic.

This article provides detail on these two points. With respect to the first point, it explains how on

SEE POSTS ON:

- Chlorpyrifos
- Glyphosate
- GM
- Other

ABOUT US/ CONTACT

Safe Food Matters Inc. is a Canadian non-profit corporation, founded in 2016, dedicated to safe food and a safe environment. We work to improve regulatory

our file Health Canada did not conduct a strong risk assessment, was not transparent, and delayed the file by more than a decade.

On the second point, it shows that the regulator: was not upfront about the process, did not provide relevant documents, did not provide the qualifications of reviewing scientists, and worked to counter rather than properly consider the objections that were presented.

Our Story

We are Safe Food Matters Inc., a Canadian non-profit corporation that promotes public health and the environment through education and fostering public engagement on safe food issues. We started this battle by filing a Notice of Objection (NoO) to Health Canada when it decided in 2017 to allow glyphosate to be used in Canada until at least 2032 – – a 15 plus year renewal.

Health Canada (HC) took 18 months to look at our objection (as well as the seven other objections that were filed), and dismissed them all in January 2019. HC said the objections did not raise "scientifically founded doubt" about the evaluation they had conducted on the risks of glyphosate.

We and the other groups were not told that we had to raise "scientifically founded doubt" (SF Doubt). Still, we thought we'd raised valid concerns about the evaluation of risks, so in February 2019 we filed for judicial review in Federal Court to make the

policies to better protect human health and the environment.

Our current topics are glyphosate, chlorpyrifos, and GM (genetically modified/edited products). To see our collections on a topic, click on the topic link in a post or on the sidebar.

We are going to court over Health Canada's 2017 re-registration of glyphosate. Please help with legal costs by donating through direct transfer to safefoodmatters @gmail.com or

case. The judge of the Federal Court dismissed our case in January 2020, disagreeing with our arguments on the scope and content of SF Doubt.

We have now filed in Canada's Federal Court of Appeal, on the basis that the judge erred in her interpretation of SF Doubt. We are asking for the lower judgement to be set aside. We are asking that the Court of Appeal find that we did raise SF Doubt. If the Federal Court of Appeal agrees, we'll ask for the establishment of an independent review panel to look at aspects of the evaluation of risks of glyphosate. Why? The establishment of such a panel is allowed if a NoO raises a SF Doubt and the advice of a panel would assist.

Friends of the Earth, Environmental Defence and David Suzuki Foundation are joining us as intervenors at the Federal Court of Appeal. Ecojustice is representing them.

Detail on the Two Reasons

We don't think safe food matters much to Health Canada because of what we've seen in our own case and those of the other objectors: we don't think HC followed the intent or letter of the law, or behaved in a manner the Canadian public and lawmakers expect.

1. Didn't Follow the Intent or Letter of the Law

a) The Law

through our GoFundMe link. Every little bit helps! Thanks.

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GoFundMe: gf.me/u/y4qsvc

Glyphosate is a pesticide. Pesticides are designed to kill (insects or weeds) and so by their very nature are dangerous. They fall under the *Pest Control Products Act* (the "Act") and are regulated by the Pest Management Regulatory Agency (PMRA), a division of Health Canada.

PMRA is supposed to make sure the risks posed by pesticides are "acceptable", in that there is a "reasonable certainty of no harm" to human health, future generations and the environment (Act s. 2(2)). The scheme of the Act sets out three main ways to ensure "acceptable risk":

1. Strong scientifically based risk assessments;
2. Transparency so the public can examine the risk assessments and the science behind them;
3. Mandatory review of main pesticides every 15 years to ensure the risks are still acceptable.

b) What PMRA Did

We believe PMRA failed on all three counts in its 2017 evaluation of glyphosate.

Not a Strong Risk Assessment.

With respect to point 1, our view is the risk assessment of glyphosate was lacking. A strong risk assessment would examine all of risks that arise from the chemical. It would be based on current, accurate scientific information and studies, and apply appropriate weighting to the information. It would use current, sound methodologies.

RECENT POSTS

- UPDATE 2: GOVERNMENT PAUSES MRL INCREASES, AND WILL REVIEW PARTS OF THE ACT; BUT MORE IS NEEDED
- UPDATE: Comment 'til Sept 3 on Glyphosate MRL increases
- HOW TO TAKE ACTION ON GLYPHOSATE
- **Health Canada Wants to Increase Glyphosate in Food**
- Corporate "Controllover" of Health Canada on Gene-Edited foods

From our perspective, these criteria were not met. One of our concerns was that the assessment did not examine a particular risk, the risk that arises when glyphosate is used as a "desiccant". Desiccation is when the grower sprays glyphosate right on the crop when it's almost ready to be harvested. Studies show that this "pre-harvest" spraying causes glyphosate to move to and concentrate at high levels in the fruits, beans and grains of the crop we eat. PMRA did not examine this risk.

Moreover, the assessment of glyphosate in the Canadian diet was based on outdated, inaccurate data and used an older methodology. It was based on what Americans ate in the 1990s, not on what Canadians eat in the 2010s. It didn't account for the massive increase in consumption by Canadians of legumes (which are desiccated) in recent years. It also used an older version of the dietary risk assessment model (DEEM) than the one that was available to PMRA at the time. (HC even admits in its own document that there are problems with its approach to dietary risk assessments).

Not Transparent.

PMRA in 2009 published the document "Getting involved in Canada's Pesticide Regulatory Process". It said it wanted the process to be transparent so the public can meaningfully participate. A public registry was supposed to provide citations to the research used in the evaluations. The public was supposed to be able to view the confidential test

data considered by PMRA in the risk assessments. Both proved to be a dismal failure.

First, the public registry is not transparent about the research used. The citations listed at the end of PMRA's preliminary risk assessment of glyphosate (called PRVD 2015-01) include unpublished research, so it cannot be seen. Further, the list includes this statement, which makes it clear that the list is incomplete:

> ***ADDITIONAL PUBLISHED INFORMATION***
>
> ***Note: Only published studies that are cited in the PRVD are listed below; a full list of published information considered in the re-evaluation is available upon request.***

The public was also not able to review the confidential test data during the time frame for the risk assessment process. PMRA opened up the reading room on glyphosate only *after* the time for submitting a notice of objection had passed! When some objectors pointed this out, they were allowed to submit their objections later, but this was obviously not fair.

And transparency was only available to those in or around Ottawa. The reason is one has to actually visit PMRA headquarters in Ottawa to view the studies. Copies cannot be taken. An affidavit has to

be signed. PMRA states that it "is aware that this may be burdensome for some requestors and is investigating alternative approaches for the future that may allow the inspection of data through other means (for example, satellite reading rooms, secure portals, etc.)". Too little too late.

Not a 15 Year Review Cycle: 39 Years for the Review!

Glyphosate was registered for use in Canada in 1976. The intent of the legislative scheme (as shown in the Parliamentary debates) was that older pesticides be re-evaluated 15 years after they are registered. Unfortunately, the Act (s. 16(2)(a)) says the re-evaluation is to be *initiated* every 15 years. In the case of the very old pesticides that were registered prior to 1995 (like glyphosate), the Act required that the re-evaluation be initiated by April 1, 2005 (s. 16(2)(b)).

PMRA did not comply with the Act and initiate a re-evaluation by April 1, 2005. The record shows an internal HC email from 2006 indicating that the re-evaluation had been started in 2006, but a follow up email stated:

> *"The re-evaluation of glyphosate is going to be postponed, probably for several years. So there is a plan to revoke the announcement that it is under re-evaluation."*

It was indeed postponed until 2009, and it wasn't until 2015 that the "proposed" re-evaluation decision was published by PMRA — a decade after April 1, 2005. Two years later, in 2017, the final re-evaluation decision was published (RVD2017-01).

2. PMRA's Conduct

Our second reason for believing that safe food does NOT matter to Health Canada is PMRA's conduct throughout this objection process. There have been problems: with the procedure not being clear; with not providing documents; with lack of disclosure on qualifications; and with the review of the objections.

a) Procedural Problems: Not Being Upfront.

The "transparency" goal of the Act wants the public to be involved in the risk assessment process. Input from the public can point out problems with the process and new information that might not have been considered.

In order to participate, the public needs to know the rules of the game. But in the glyphosate case, the PMRA did not tell the public that they had to raise a "scientifically founded doubt" about the validity of the re-evaluation. It is not mentioned in the publications of the proposed and final re-evaluation decisions, PRVD2015-01 and RVD 2017-01. The wording is set out in the *Review Panel Regulations,* but many objectors did not know about

these regulations, or thought they were about something other than the required content for an objection.

This perception was underlined by PMRA. One objector was told by PMRA's Charles Smith (Senior Science Coordination Officer, Registration Directorate, who appeared to be point for communicating with the objectors), that:

> *"The Regulations deal with the enforcement of the PCP Act and* ***not the process by which submission/applications are actually reviewed "****.*

PMRA finally told the objectors about the regulations on January 11, 2019 in a telephone call. This was the date when PMRA dismissed the objections: it was 18 months after the objections were filed. Too little, too late.

b) Not Providing Documents

During the court case, we saw a reference in PMRA's record to a draft Discussion Document authored by PMRA. The document discussed several criteria for finding this "scientifically founded doubt about the validity of the evaluations". The PMRA's record was supposed to contain everything relevant, so we thought they'd just missed putting it on the record at the lower court level. But when we asked for it to be put on

the record for the appeal, they refused. We had to go to Court to ask for it, but were not successful.

A second document we consider relevant was in a file provided to another objector pursuant to an *Access to Information* request. It contained an email exchange that spoke about the wording of PMRA's response to our objection. It shows that the wording in the final version we received had changed. Again, this was not provided to us.

A third document was a key study on "white beans". This 1992 study formed the entire basis for allowing glyphosate spraying on chickpeas. It shows that spraying on these crops has never been looked at, rather this "white bean" was used as a proxy for chickpeas. It also shows that the reviewers had some concerns about this study. We asked for a copy of the study, and PMRA said it was coming, but never provided it — until we went to court. It showed up in the record they provided to us.

c) Not Providing the Qualifications of the Evaluating Scientists

On January 11, 2019 Health Canada issued a press release that stated it was rejecting all eight of the NoOs. The press release included this statement:

> *"To help ensure an unbiased assessment of the information, Health Canada **selected a group of 20 of its own scientists** who were*

> *not involved in the 2017 re-evaluation to evaluate the notices of objection."*

One of the objectors, Ms. Josette Wier, asked for the qualifications of these 20 scientists (among other things). After many e-mail exchanges and rewordings, she made clear her request:

> *"My question remains regarding the qualifications required by Health Canada/PMRA for defining a "scientist", in particular for assessing the scientific literature associated with the evaluation of glyphosate."*

The PMRA has to date not provided the qualifications required by PMRA for the scientists involved with the evaluation of glyphosate. It has said it "employs a diverse range of scientists" and referred her to the general qualification standards for the public administration.

The case law on this point states:

> *The **requirements and qualifications for a position** are indeed determined by the government institution, and **their disclosure to the public meets the objectives of federal access to information legislation**, namely, to increase transparency in*

> *government, contribute to an informed public and enhance an open and democratic society. (Nault v. Canada 2011 FCA 263, [2013] 2 FCR 491)*

It is also not even clear that twenty scientists were involved in the actual review of the NoOs, meaning actually working "on the file" as "evaluators". It appears from the record that only **eight** people met in June 2018 on the issue of responding to the NoOs. A recent letter sent to Ms. Wier from the Information Commissioner of HC references only "**eight** individuals involved in the re-registration of glyphosate".

After Ms. Wier asked questions about the scientists, internal emails from HC questioned the number twenty, stating:

> *"We had only one principal EAD [Environmental Assessment Directorate] evaluator on the file ……, but if the agency count is 20, were other people from EAD included?* ***That seems like a lot of people for this file.*** *I was thinking perhaps names of a peer reviewer or minor contributors from EAD might have been pass on to whomever prepared the list of names. Could you please let me know who is on the list from EAD?"*

The response was merely, “As for the number, yes it included peer reviewers and section heads”. Elsewhere the same person responded there were an “indeterminate” number of Health Canada employees, including senior evaluators, section heads and directors. Peer reviewers, section heads and directors are not evaluators.

We believe disclosure of this information is integral to the risk assessment process. In Europe, there is a whole set of rules around this, including the rule that “The procedures used for the selection of experts should be transparent and applied in a consistent manner”.

d) Dismissing Rather than Considering Whether the Objections Raised SF Doubt

In responding to the various glyphosate objections, it appears PMRA’s focus was on dismissing rather than considering whether the objections raised SF Doubt about the risk evaluations of glyphosate. Internal meeting notes show that when looking at many of the objections the main focus was on finding the right wording to dismiss the objections (from previous responses, other chemicals, other regulatory agencies). Various tactics were used to dismiss the objections. For example, PMRA would not respond to points raised, or mischaracterize the points so they could be dismissed.

PMRA used one tactic in particular on several occasions. In its response to an objector, it would

first say "We didn't look at that particular issue or risk in the risk assessment", and then move on and purport to look at the issue or risk in their response to the objector. But the proper place for such an analysis was in the risk assessment, not these responses. In our view, the fact that PMRA provided an analysis "after the fact" shows there was a gap in the initial evaluation.

Three examples are set out below.

Example 1: Glyphosate's Impact on the Human Microbiome

One objector raised concerns about PMRA's review of glyphosate's impact on the human gut, or microbiome. She indicated the review was in inadequate, in that:

> *"There was absolutely no scientific evidence presented to indicate that independent studies have ruled out an impact on the microbiome or that such studies have even been undertaken".*

PMRA's response indicated that it **does not require studies on the microbiome (WE DON'T ASSESS THAT RISK)**, even though the Act allows PMRA to ask the chemical company to provide additional data for the risk assessment, and if it does not then the Minister can remove the pesticide from the market.

PMRA then proceeded to *look at the issue itself and dismiss it*. It said that it looks for signs of toxicity on the gut, and to PMRA this is "**considered protective** of potential effects on the gastrointestinal tract". In our view, this is not a satisfactory response if problems can arise in the gut that may not be associated with toxicity in the gut.

Other objectors raised the issue concerning the microbiome, and again PMRA *looked at the issue itself and dismissed it*. The objectors pointed to eight animal studies in the Reading Room that showed signs of microbiome effects in animals, and indicated further study was required. PMRA responded that there is information on the impact to the gut based on "in vitro" studies (meaning studies in in a test tube or laboratory dish), but then *dismissed the issue* with the statement that the evidence from "in vivo" studies (meaning studies on animals) is very limited and inconclusive.

So even though there was evidence of a problem (evidence (in vitro), the chemical company was not asked for "in vivo" information.

PMRA also *dismissed the issue* with the same type of "gut toxicity" explanation provided above. It indicated that the doses in Canada are lower than those that cause system toxicity and so the doses "are therefore protective of potential effects of the gastrointestinal tract".

Example 2: Glyphosate Chelates Minerals/ Metals

Objectors raised the point that glyphosate chelates (binds with) vital minerals in soil and plants, and this could lead to depletion of essential minerals and/or mobilization of some toxic metals in soil and plants, including perhaps cadmium which has been found in wheat.

PMRA responded with "PMRA does not currently assess the risk of the chelating potential of pesticides" **(WE DON'T ASSESS THAT RISK)**. It continued with the statement "however, the information provided in the NoO relevant to this comment was *examined to determine whether it provides compelling evidence* impacting the validity of the glyphosate risk assessment document". It found that the one study provided was not compelling, then *PRMA looked at the issue itself and dismissed it.* It provided its own explanation that "**it is not expected** that glyphosate will significantly affect the uptake of metals by plants in most situations".

Example 3: Glyphosate's Impact on Soil

Objectors raised the concern that the "PMRA failed to consider evidence of the effects of glyphosate on soil microbiomes". PMRA responded with its previous statement "PMRA does not assess risks to soil microorganisms" **(WE DON'T ASSESS THAT RISK)**.

However, PMRA then made the same statement as above, namely that it examined the information provided in the NoO to determine whether it provided "*compelling evidence* impacting the validity of the glyphosate risk assessment document". It added "Other sources of information were also consulted, for completeness".

PMRA then took it upon itself to go on for eight paragraphs, the longest response for any of the objections, to ACTIVELY COUNTER the evidence presented in the objection. The evidence of the objectors showed adverse effects of glyphosate on individual microbial species and communities, and PMRA even agreed that glyphosate affects individual species and "could cause a shift in the assemblage of the soil microbiome". But then PMRA pointed to other studies to suggest that some soil is not affected and that some soil activities may not be or are not affected.

When PMRA looked at the studies provided by the objectors, it did not disagree with them. It even agreed that one particular group of studies "indicated that glyphosate caused adverse effects on mineral nutrition, microbial species/community and microbial activities in the soil of GR crop". To us, this appears to raise a doubt based on scientific studies that warrants further review.

But instead PMRA countered the doubt with "a literature review of more than 8000 relevant peer-reviewed papers (Duck and Lydon, et al, 2010)" that disagreed. (Even though in its response on another

objection it *discredited* review article information because "the review articles themselves, are not actual studies, but a summary of several individual studies").

PMRA described this as a situation of "conflicting results", then took it upon itself to provide an explanation for "these conflicting results on the effects of glyphosate exposure on the soil microbiome". The explanation resulted in PMRA dismissing the objection.

Summary of Examples.

In our view, the required scientific doubt was raised in each of these three examples by the very fact that the evaluation **didn't assess these three risks** that had a scientific basis. In our view the independent review panel should have been struck.

Instead, the PMRA it took it upon itself to do the job of the independent panel, without having the scientific evidence that such a panel would require. It provided explanations ("it is not expected" , "is considered protective") without having data. It found conflicting science, brought in studies not previously considered, and even resorted to literature reviews it elsewhere discredited. And then came to its own conclusions and dismissed the objections.

This is not what the Act or the legislators had in mind. If it was, when could a review panel ever be

struck?

Conclusion: Safe Food, and Other Risk Areas, Require Improvement

Because safe food matters, we are working in the court system to get the PMRA to conduct proper risk assessments on pesticides that affect our food.

Our hope is for improved risk assessment and objection processes that can be applied in other areas where there are risks to our health, risks to the environment, and risks to future generations. Because we are living in a world of high risk; now, perhaps more than ever before.

Please support us and help cover our legal costs in our David vs. Goliath battle.

Related

Why is Glyphosate Still Allowed In Canada?
2021-06-01
In "Glyphosate"

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2021-08-08

Objecting to Glyphosate Desiccation
2017-10-30
In "Glyphosate"

This is **Exhibit "D"** referred to in the affidavit of **Mary Lou McDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 3rd day of November, 2021.

Commissioner for Taking Affidavits
(or as may be)

To: Minister of Health Patty Hajdu, PC, MP
c/o Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, Ontario AL: 6606D2 K1A 0K9
By Email to: hc.pmra-info-arla.sc@canada.ca
And to: hcminister.ministresc@canada.ca

February 8, 2021

Re: Notice of Objection to the Re-Evaluation Decision RVD2020-14 Chlorpyrifos and its Associated End-use Products (Environment)

Dear Minister Hajdu,

We are writing to present our objections to the evaluation of environmental risks and value taken by the Pest Management Regulatory Agency ("**PMRA**") as set out in the May 31, 2019 Proposed Re-evaluation Decision PRVD2019-05 *Chlorpyrifos and Its Associated End-use Products: Updated Environmental Risk Assessment* ***("PRVD 2019")*** and the December 10 *Re-Evaluation Decision RVD2020-14 "Chlorpyrifos and its Associated End-use Products (Environment) ("**RVD 2020**")*. There are concerns with the scientific analysis undertaken and the conclusions reached during the risk assessment process embodied in PRVD 2019-05 and RVD 2020-14. We herein present the scientific basis for the objections, and the evidence to support the objections.

The overall conclusion of PRVD 2019 and RVD 2020 (collectively, the "**Evaluations**") was that that certain risks are "acceptable" with required mitigation measures. The standard for whether a risk is "acceptable" is set out in Section 2(2) of the *Pest Control Products Act* (the "Act"), and it requires that there must 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 its conditions or proposed conditions of registration". We have a fundamental concern with this conclusion, and also specific objections, all of which will be outlined below.

1. Fundamental Concern with the Conclusion.

As discussed in PMRA's own "*SPN2000-01: Technical Paper A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*" ("**Decision Framework SPN2000-01**") if a risk is unacceptable, then PMRA can try to put in place risk management options, but these have to "reduce the identified risk(s) in such a manner and to such an extent that the pesticide can be used **without unacceptable risks** to health and the environment" (p.14). In other words, the PMRA still has to have a certainty that is reasonable that no harm to the environment will result from exposure to the product after the proposed conditions of registration are put in place, because the standard of "no harm" is what is required by the Act. The standard is not whether there is a reduced harm, but rather whether there is any harm.

The risk mitigation measures set out by PMRA at RVD p. 3 set out amendments to labels detailed in Appendix V, and PMRA in the Evaluations explains how measures taken are expected to minimize or reduce the risk. These will be discussed in more detail below. PMRA indicates in PRVD that "minimizing" risks to certain groups will allow for risks to be acceptable:

> "Risk from chlorpyrifos has not been shown to be acceptable to aquatic biota, beneficial arthropods, birds and mammals. From an environmental perspective, only uses that **minimize** or eliminate exposure to these groups are acceptable for continued registration".

Because these measures seek to minimize or reduce the harm, not eliminate it, they do not comply with the standard set by the Act, with the result that the conclusion that risks from the permitted uses are "acceptable" is not valid. This raises a fundamental concern regarding the conclusion of the Evaluations.

2. Specific Objections on the Listed Uses

Apart from this basic concern, there are other concerns with the analysis PMRA presented in the Evaluations of each of the uses that is still permitted. The decision of PMRA in RVD is that all outdoor uses of chlorpyrifos are cancelled except for those listed, because risks to the environment for the cancelled uses "have not been shown to be acceptable" (p.2). It stated that "[t]he following uses are acceptable from an environmental perspective with required mitigation measures:

- Standing water – temporary pools for larval mosquito control.
- Outdoor adult mosquito control.
- Structural indoor and outdoor (non-residential).
- Outdoor ornamentals (contained stock room immersion only) for control of Japanese beetle larvae.
- Elm bark beetle and mountain pine beetle control.
- …… "

We will herein call these uses the "**Listed Uses**". In saying that "the follow uses are acceptable", the PMRA is saying that the risks associated with such Listed Uses are acceptable, meaning: there is a certainty that is reasonable that no harm to the environment will result from exposure to or use of the product when used for the Listed Uses, taking into account the relevant mitigation measures.

The objections below present concerns with the assessment of chlorpyrifos conducted by PMRA. The objections are scientifically based, meaning they speak from the perspective of current scientific approaches and methodologies, in many cases as pronounced by the PMRA itself. They provide rationales and arguments based on science and the methods of science, as well as evidence in support, that show concerns with the assessments of risk and value associated with the use of chlorpyrifos for the Listed Uses. Each Listed Use will be addressed separately.

First, a basic understanding of the fate and behaviour of chlorpyrifos in the environment is presented for background.

Background.

As background to the objections presented below, scientific information on the fate and behaviour of Chlorpyrifos in the environment will be discussed

Enters surface water by way of runoff from soil: First, Chlorpyrifos has a half-life in aerobic soil that is longer than that in aquatic systems. PMRA states (p.29 of RVD): "With a longer half-life in soil and low mobility, chlorpyrifos bound to soil products will remain in the top layer of the soil and can enter surface water through runoff as surface soil particles are dislodged due to rainfall. Concentrations entering surface water bodies from runoff were found to be of concern given the high toxicity of chlorpyrifos to aquatic life".

Volatilization: Chlorpyrifos is subject to rapid volatilization to a significant degree. Field studies indicate dissipation from plants has two phases, first "rapid volatization" followed by photolysis and growth dilution. (PRVD 2019 p.6). Also, "[l]aboratory studies indicate volatization is unlikely to contribute significantly to dissipation of chlorpyrifos in the environment; however field studies demonstrate that volatization is significant (25-80% of applied chl)".

Because chlorpyrifos is volatile or semi-volatile, it moves by the "grasshopper effect" and is transported long distances. The "grasshopper effect" is described as follows: "In a process known as global distillation, prevailing ocean and wind currents bring contaminants to the Arctic where they are subsequently trapped by the cold climate. This process is often referred to as the "grasshopper effect," as chemicals repeatedly evaporate and condense while in their journey toward the Arctic". The October 2020 *Draft proposal for listing chlorpyrifos in Annex A to the Stockholm Convention on Persistent Organic Pollutants* of the European Chemicals Agency describes the long-distance transport.

Persistence: PRVD2019-05 at pp. 5,6 indicates chlorpyrifos is non-persistent to moderately persistent in Canadian or equivalent soils (half-life = 11–180 days) (DT50 = 2-56 days), with persistence decreasing with increased soil alkalinity. In *Proposed Acceptability for Continuing Registration - PACR2003-03* ("**PACR2003-03**") PMRA stated the chlorpyrifos is persistent.

A. Objections Re: Listed Use: Standing water – temporary pools for larval mosquito control.

With respect to this use (and most of the other Listed Uses), the conclusion of the science evaluation of PMRA was (p. 27 of PRVD):

> "Greenhouse ornamental, outdoor ornamentals (container stock only) for control of Japanese beetle larvae, indoor and outdoor structural, adult and larval mosquito uses of chlorpyrifos are considered to be acceptable from the environmental perspective **due to the limited potential for environmental exposure**." The ("**Limited Exposure Conclusion**").

With respect to the particular use of standing water – temporary pools , PMRA stated (p.25 of PRVD):

> "Although use of chlorpyrifos to control mosquitoes will result in release to the environment, environmental risk was deemed to be acceptable. Larval mosquito control is restricted to temporary pools and standing water and the presence of aquatic biota in these systems is expected to be limited".

And in response to a comment in RVD (p. 21) it stated:

> "Temporary pools are ephemeral in nature resulting from flooding of or drainage to low-lying areas and are not seasonal or permanent habitats. Health Canada acknowledges that while temporary pools may contain invertebrates and amphibians, their ecological function as a habitat is limited by their short duration during the growing season and as such do not require a separate risk assessment. In addition, it is not relevant to conduct a temporary pool risk assessment for drift or runoff resulting from adult mosquito control as chlorpyrifos is registered for direct application to such pools for mosquito larvae control."

The concerns with these evaluations on standing water and temporary pools by PMRA are the following:

i) First, PMRA did not assess the exposure to the environment from this use on standing water and temporary pools, apart from stating that the function of temporary pools as a habitat is limited. PMRA sets out the methodology to be used when assessing environmental exposure in its document *SPN2000-01: Technical Paper A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*" ("**Decision Framework SPN2000-01** (at 9):

> "To estimate environmental exposure to pesticides, it is essential to know how, when and under what conditions a pesticide is being used **and to predict from its behaviour and fate in the environment the extent of exposure** (concentrations in soil, surface and ground water) at the use site and in other environmental compartments".

PMRA did not predict the extent of exposure at the use sites of standing water and temporary pools based on its knowledge of the behaviour and fate of chlorpyrifos in the environment. It did not speak to exposure in terms of concentrations in soil, surface or ground water or other indicia at the site of temporary pools or standing water. This represents a concern with not applying the correct methodology, and also with a failure to provide evidence or analysis. It cannot be said that a finding is "reasonable" and that there is a certainty of no harm that is reasonable, without providing support. This failure to provide an analysis of the extent of exposure is common to many of the Listed Uses, as will be seen below. With respect to the List Use on larval mosquitos, PMRA did not provided information on the extent of exposure, but merely stated that the presence of aquatic biota is "expected to be limited".

There is also a concern with the statement by PMRA that temporary pools do not require a separate risk assessment because: "their ecological function as a habitat is limited by their short duration during the growing season", and that "it is not relevant to conduct a temporary pool risk assessment for drift or runoff resulting from adult mosquito control as chlorpyrifos is registered for direct application to such pools for mosquito larvae control". However, the focus of the analysis of PMRA is misdirected on this point. The focus of the assessment is not of the use, but of the product and how it behaves in the environment when it is used, regardless of whether the ecological function of the use site or the particular components of the environment that are affected are temporary or not. In fact, Environment

Canada, in *Overview of the Ecological Assessment of Substances under the Canadian Environmental Protection Act, 1999,* requires a Use Pattern Analysis and this includes "temporal use patterns" (p.13).

Because PMRA did not conduct a risk assessment, it did not assess the effects of this use on other relevant indicator species, such as birds and mammals, even though **Decision Framework SPN2000-01**" states (at 9) that the potential effects in non-target biota are to be assessed and characterized using internationally recognized indicator species.

The lack of assessment is particularly problematic, because the number of temporary pools and pools with standing water in Canada is likely very large. For instance, there are likely a large number of farm pools in the prairie provinces while agricultural activities occur on a large scale, based on the experience in the Great Plains of the United States. The authors of the study on the Great Plains of the United States estimated 376 209 permanent ponds and 201 445 temporary ponds were in their study area and concluded that "Because permanent and temporary farm ponds are abundant and have different physicochemical properties and ecological communities, assessments of regional biogeochemical processes and biodiversity in the Great Plains must consider both types of ecosystems". [Matthew M. Chumchal, Ray W. Drenner & Kimberly J. Adams (2016) Abundance and size distribution of permanent and temporary farm ponds in the southeastern Great Plains, Inland Waters, 6:2, 258-264 https://doi.org/10.5268/IW-6.2.954]

Temporary, ephemeral or vernal pools are essential to biodiversity and at-risk species, as exemplified in Parks Canada Recovery Strategy Series, July 2006, *Recovery Strategy for Multi-Species at Risk in Vernal Pools and other Ephemeral Wet Areas Associated with Garry Oak Ecosystems in Canada*. [https://www.sararegistry.gc.ca/virtual_sara/files/plans/rs_Vernal_pool_0806_e.pdf]

ii) Second, the information used and assumptions made by PMRA to come to its conclusion that "there is limited potential for environmental exposure" from this Listed Use are not accurate or plausible. The scientific information used in a risk assessment must be accurate. With respect to assumptions made, risk assessments are to ensure the assumptions meet high standards of plausibility. The requirements of risk characterization as set out by the National Research Council (1996) *Understanding Risk: Informing Decisions in a Democratic Society,* adopted by Health Canada in its explanation of the risk assessment process for health (Health Canada *Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* - August 1, 2000), requires that assumptions be plausible (p. 33):

> "*Get the Science right:* Ensure the underlying analysis meets high scientific standards in terms of measurement, analytic methods, databased used**, plausibility of assumptions**, and consideration of both the magnitude and nature of uncertainty…".

One assumption PMRA made was that "the presence of aquatic biota in these systems is expected to be limited". Another is that the ecological function of temporary pools as a habitat is limited. It appears PMRA is speaking of limits in terms of time, as evident by the use of the words "short duration". However, the fact that the presence of water in a pool may be limited by time does not mean that there a few aquatic biota in the pools, or that their function as an ecological habitat is limited.

Temporary pools are homes to many species, both while the water is present and afterwards. The conclusion of a recent study was that aquatic insect communities inhabiting temporary habitats are diverse, and include several species that frequently inhabit these environments due to their biological adaptations [Thanya Reunura & Taeng On Prommi, *Aquatic Insect and Factors Influencing their Abundance in Temporary Habitats*, Journal of Food Health and Bioenvironmental Science (May - August 2020), 13(2): 17-27 at 25]

Moreover, temporary pools are not limited with respect to their ecological function. They have their own ecological function and species that adapt to the temporary nature of the pools. The pools "are colonized by organisms with short life cycles that are well adapted to temporary habitats" [Heiss, J.S., Harp, G.L., & Meisch, M.V. (1986). Aquatic Coleoptera associated with Arkansas rice, with observations on the effects of Carbofuran, Molinate, predatory fish and late-planting. The Southwestern Naturalist, 31(4), 521-525Heiss et al., 1986]. They also contain unique set of species in need of protection. [BLAUSTEIN, LEON & Schwartz, Steven. (2001). Why study ecology in temporary pools? J Zool. Israel Journal of Zoology - ISR J ZOOL. 47. 303-312. 10.1092/CKMU-Q2PM-HTGC-P9C8.]

A March 2009 study identified 86 insect species in temporary pools of water in an urban area [Fontanarrosa, M. Soledad; Marta B. Collantes; and Axel O. Bachmann (2009). "Seasonal Patterns of the Insect Community Structure in Urban Rain Pools in Temperate Argentina." Journal of Insect Science, 9(1).] Field studies in North Carolina between 1974 and 1990 identified over 150 species of insects in temporary pools [HM Wilbur (1997), "Experimental Ecology of Food Webs: Complex Systems in Temporary Ponds." Ecology Journal, 78(8): 2279–2302]. A comparison of biota in temporary pools in the United Kingdom, Australia and northeastern North America found a wide diversity of insect species. [DD Williams (1998). "Temporary pools and their invertebrate communities." Marine Conservation, 7(2)].

iii) Third, there are concerns specifically with PMRA's understanding of the temporary nature of pools. PMRA indicates that the use is on **both** standing water and temporary pools, and then takes the position that there are not concerns because temporary pools are "ephemeral in nature". It indicates "temporary pools" as those "resulting from flooding of or drainage to low-lying areas and are not seasonal or permanent habitats".

The first concern is the error of omission with respect to "standing water", which forms part of the target of registered use. Standing water is not necessarily ephemeral in nature. By way of example, sloughs are often permanent, but are characterized by standing water or water that flows slowly. Generally, they are their own microhabitats high in species diversity, including vegetation, aquatic species and birds. [See the scientific literature and studies cited in Wikipedia on the topic "Slough (hydrology)"].

The second concern is that the determination of whether a pool is "temporary" can only be made after the fact of chemical application: it may be that a pool becomes permanent because of additional and unexpected rain or unexpected drainage from other sources. Additional rain has been an issue in the prairie provinces, as in 2014 when rainfall on the eastern prairies was extreme and a state of emergency was called [Rod Nickel, *Rain causes states of emergency in eastern prairies*, Western Producer, June 30, 2014]. As such, there is a risk that application of chlorpyrifos to a pool that was considered at the time of application and expected to be "temporary" will affect aquatic biota in what becomes a permanent pool. This raises issues of the efficacy of the labels and means there can be no certainty that no harm to the environment will result from exposure to or use of the product.

iv) Fourth, the science indicates that the behaviour of chlorpyrifos is such that it will cause environmental harm. Once it hits the water it sinks to and sorbs to the soil on the bottom because, as stated by PMRA, it has a longer half-life in soil than in aquatic systems and low mobility (Reference). That chlorpyrifos sinks when it lands on water is supported by the following statement from the EPA in Appendix 3-1 to Chapter 3: Chlorpyrifos Exposure Characterization for ESA Assessment, forming part of the "Biological Evaluation Chapters for Chlorpyrifos ESA Assessment (p. B3(FC)-9).

> "In general, chlorpyrifos is uniformly distributed in the 30 cm of overlying water within 24 h and moves into the sediment within 30 days but does not penetration below 2.5 cm depth.

> Chlorpyrifos was observed to persist beyond 30 d with a dissipation half-life of 20 days (spring applications)"

That chlorpyrifos sinks into sediments is also supported by the following scientific studies:

- Bromilow, R. H., De Carvalho, R. F., Evans, A. A., and Nicholls, P. H. (2006). Behavior of Pesticides in Sediment/Water Systems in Outdoor Mesocosms. J.Environ.Sci.Health Part B 41: 1-16
- Toshiyuki. Pesticide Behavior in Modified Water Systems. J. Pestic. Sci. 41(4), 121–132 (2016) DOI: 10.1584/jpestics. D16-060

Once chorpyrifos is in the sediments it will "remain in the top layer of the soil…" , as stated by PMRA, and then, once the temporary pool is drained or evaporates, it "can enter surface water through runoff as surface soil particles are dislodged due to rainfall" (RVD p. 29). Thus it can be predicted that direct application of the pesticide to temporary pools will likely result in runoff to surface water. Thus PMRA was in error when it indicated that because chlorpyrifos is registered for direction application to pools that it is not relevant to conduct a temporary pool risk assessment for runoff.

v) Fifth, environmental harm can be predicted even with direct application, beyond the already documented harm to aquatic biota found in PRVD 2019. Chlorpyrifos causes blue-green algae grown to increase, as reported by the EPA (Grows blue-green algae (APPENDIX 2-3. Open Literature Review Summaries for Chlorpyrifos) Biological Evaluation Chapters for Chlorpyrifos ESA Assessment | Protecting Endangered Species from Pesticides | US EPA:

> "The blue-green alga, Anabaena flos-aquae, and the green alga, Chlamydomonas reinhardii, both showed stimulation of growth when exposed to chlorpyrifos. The increase in growth was approximately 20% at 10 µg a.i./L and 60% at 100 µg a.i./L for A. flos-aquae; and 18% at 100 µg a.i./L for C. reinhardii (see Table 1)."

vi) Finally, there are concerns with the evaluation of value of this Listed Use. With respect to the value of chlorpyrifos for the use of mosquito control, PMRA in PRVD (p.26) indicated it is one of the few insecticides registered to manage mosquito larvae, and stated:

> "Chlorpyrifos is valued **in mosquito larval control** programs for rotation with other insecticides to delay the development of insecticide resistance, **since mosquitos have been documented to develop resistance**." (PRVDp.26)

The document *Regulatory Directive DIR2013-03, Value Assessment of Pest Control Products* ("**DIR2013-03 Value Assessment"***)* of PMRA discusses the value of delaying resistance in the context of making a choice among pesticides in terms of value: the one that delays resistance is preferred to one that does not. It states:

> ''The PMRA also considers the potential impact on resistance development and the role a pesticide plays in the management of pesticide resistance. The introduction of a pesticide with an existing mode of action may accelerate the development of resistance, while a pesticide with a new, unique mode of action may provide the opportunity to delay the development of resistance, thus increasing its value.''

One concern is that in neither RVD or PRVD did PMRA provide an explanation of how the mode of action of chlorpyrifos provides an opportunity to delay resistance in mosquitos to other insecticides used on temporary pools and standing water.

Another concern is the proposition for value of delaying resistance is not supportable. The value with respect to mosquito larval control as indicated by PMRA appears to be that rotating chlorpyrifos out with other insecticides will help delay the development of resistance of mosquitos to other insecticides. However, mosquitos develop resistance very quickly and easily, such that the value proposition is not supportable. In addition, it appears that the application of pesticides actually exacerbates the problem or resistance because resistance develops more quickly in areas subject to spraying than in those that are not.

The statement that mosquitos develop resistance easily is supported by a 2003 study that found that all that was required was a 'single amino-acid substitution in the enzyme" in order for mosquitos to become resistant to organophosphate and carbamate insecticides: (Weill, M., Lutfalla, G., Mogensen, K. et al. Insecticide resistance in mosquito vectors. Nature 423, 136–137 (2003). https://doi.org/10.1038/423136b)

Mosquitos also develop resistance quickly. For example, a recent study found that an insecticide that was about to be widely deployed would be generally ineffective: as many as 55% of the mosquitos survived spraying with the insecticide in the study, and described in this article, and found in the relevant study: [Munyaradzi Makoni, *Some mosquitoes already have resistance to the latest weapon against malaria*, August 31, 2020, Science, referring to "Centre for Research in Infectious Diseases, Resistance of Anopheles gambiae to the new insecticide 1 clothianidin associated with unrestricted use of agricultural neonicotinoids in Yaoundé, Cameroon, August 7, 2020, https://doi.org/10.1101/2020.08.06.239509").

The explanation for rapid development of resistance by the mosquito is that the life cycles of the mosquito is very short, which means that even a small number of resistant mosquitos can rapidly repopulate. Moreover, resistance develops more quickly in areas that have had previous applications of insecticides as compare to those that have not, leading to the conclusion that applying insecticides is exacerbating the problem of resistance. [Beyond Pesticides, *Pesticide Use Kills off Mosquito Predators Faster than Target Mosquitos*, June 6, 2019][Weathered, J., Hammill, E. Adaptation to agricultural pesticides may allow mosquitoes to avoid predators and colonize novel ecosystems. Oecologia 190, 219–227 (2019). https://doi.org/10.1007/s00442-019-04403-2.

Recent research shows that mosquitos have developed resistance to all four of the traditional classes of approved adulticides, namely pyrethroids, organochlorines, carbamates and organophosphates. The authors state that the results from the study are concerning. [Oumbouke, W.A., Pignatelli, P., Barreaux, A.M.G. et al. Fine scale spatial investigation of multiple insecticide resistance and underlying target-site and metabolic mechanisms in Anopheles gambiae in central Côte d'Ivoire. Sci Rep 10, 15066 (2020). https://doi.org/10.1038/s41598-020-71933-8]

The third problem with the value assessment is that chlorpyrifos is no longer valued for mosquito larval control in Canada, so the discussion of whether it is to be preferred because it can delay resistance is not relevant. The PMRA in its previous document, PACR 2002-03 *Proposed Acceptability for Continuing Registration* that deal with agricultural and forestry uses, did not provide a value proposition for this use. In its description of the use of mosquito control, it indicated the provinces of Alberta and Manitoba requested the use be maintained, presumably because at that time it was used by the Cities as Winnipeg and Edmonton, as is evident from this statement (p.32):

> **"5. Mosquito control uses**
> The registration to control mosquito larvae (aerial or ground application) will be

> maintained for granular and liquid products at the request of the provinces of Alberta and Manitoba, but will be limited to use in temporary pools only in **outlying areas of municipalities** and to **situations where the principles of integrated pest management (IPM) continue to be incorporated into the program, e.g., larval population surveys before treatment.** The use in temporary pools only, as opposed to permanent water bodies, will mitigate potential for damage to non-target aquatic organisms, which are very sensitive to chlorpyrifos. This use also has limited potential for exposure to bystanders. **Currently, the product is used in this way only by the municipalities of Edmonton and Winnipeg and with provincial authorization."**

Since that time, the Cities of Edmonton and Winnipeg have discontinued this use of chlorpyrifos for larval mosquito control. The webpage of the City of Edmonton indicates that city "utilizes a larvicide product containing Bti, a selective fly gut toxin derived from bacteria (Bacillus thuringiensis israelensis)) (Reference here). The webpage of the City of Winnipeg indicates that city uses a combination of biologicals and biorational larvacides, described as follows: The City uses the following biological larvicides: Bacillus thuringiensis var. israelensis, known as Bti under the trade names Vectobac® 200G and Vectobac® 1200L, and the City uses the following biorational larvicides: Methoprene under the trade name Altosid® - Granular (methroprene) and Altosid® - Liquid (methroprene). Since the initial users of chlorpyrifos for this use no longer so use it, there is no need for this use to be permitted.

With respect to the value assessment, PMRA is to consider lower risk alternatives. One goal of the pest control system is to facilitate "access to pest control products that pose lower risks, and encouraging the development and use of alternative, non-toxic, ecological pest control approaches, strategies and product", as indicated in the preamble to the PCPAct. Since chlorpryrifos is not used for larval mosquito control, and lower risk alternatives exist and are being used, the value proposition for this Listed Use is not strong.

B. Objections Re: Listed Use: Outdoor adult mosquito control.

The conclusion of the Science Evaluation on the Environment was that the adult mosquito use was considered acceptable due to the limited potential for environmental exposure (PRVD p. 27). PMRA provided the explanation that:

> "Chlorpyrifos can be applied by ultra-low volume (ULV) applicators for adult mosquito control. Spray droplets from ULV applications are very small and **do not deposit onto soil or water as quickly as larger droplets and are very likely to dissipate or evaporate while suspended in air**. Risk from ULV applications is considered to be acceptable to non-target terrestrial and aquatic biota." (PRVD p.25).

IN RVD 2020, PMRA characterized one comment as follows: that the environmental assessment for mosquito control in standing water and terrestrial areas does not fully characterize the risks to non-target aquatic and terrestrial organisms from direct application and spray drift. (The actual comment provided to PMRA on this point was that the potential exposure pathway for non-target insects, as well as birds, from mosquito control uses requires further examination, and that risks from spray drift and leaching associated with mosquito control uses do not appear to have been assessed). PMRA in its response spoke in RVD (p.21) to pollinators,

beneficial arthropods and birds, temporary pools (already discussed), and the use of Ultra Low Volume (ULV) applications. It stated:

> "Risk to non-target terrestrial and aquatic organisms were taken into consideration in PRVD2019- 05. The rates used for mosquito control (13–53 g a.i./ha) are within the range of application rates examined for the drift risk assessment (12–2304 g a.i./ha × 3 applications). The results of this assessment are presented in Appendix III, Table 16 of PRVD2019-05.
>
> The risk to pollinators and beneficial arthropods from adult mosquito control was quantitatively assessed in PRVD2019-05. Pollinators are not expected to be present in the evening or at night when chlorpyrifos is applied for mosquito control and beneficial insects are also not expected to be present while foraging during this time.
>
> Regarding the risk to flying birds resulting from adult mosquito control, the duration of airborne drift and its rate of dispersal in the atmosphere as well as its deposition rate indicates this exposure is negligible and as such, is not considered by Health Canada. The USEPA (PMRA# 2824701) did state: "Toxicity data are not available for inhalation exposures involving birds; however, in an acute inhalation study with laboratory rats, no mortality was observed at 0.2 mg a.i./mL-air (200 mg/m3) which is equivalent to >5,000 mg a.i./kg bw. Due to a lack of observed toxicity in this study, inhalation exposure is not considered to be of concern…".
>
> …. [Discussion of Temporary Pools]
>
> Although PRVD2019-05 refers to ULV applications, Health Canada acknowledges that terminology should have been more specific. Ultra Low Volume (ULV), also known as aerosol generation or cold fogging is intended to generate a cloud of Extremely Fine (ASABE) droplets that will stay suspended in air long enough to come into contact with mosquitos in flight. The registered mosquito uses for chlorpyrifos specify the use of mist blowers. Mist blowers are designed to release Very Fine (ASABE) droplet sizes and generate a mist cloud that settles on surfaces to control adult mosquitos in cryptic habitat, such as the undersides of leaves, vegetation and structures where the gravid or engorged female mosquitos rest. Site characteristics, as specified on the labelled uses (in other words, shallow, grassy depressions; industrial parks; roadway ditches; railway marshalling yards; small temporary sloughs; flooded woodlands) will intercept the mist cloud and result in a reduction in exposure to non-target organisms."

The concerns with the evaluations on the Listed Use of outdoor adult mosquito use are set out below.

i) PMRA again did not perform a valid assessment of the exposure to the environment from this Listed Use. In RVD p.21 PMRA stated in response to Comment 1.1.5 that the risk to pollinators and beneficial insects from adult mosquito control was **quantitatively assessed** in PRVD2019-05. However, there is no evidence or data that supports a particular quantitative assessment associated with this Listed Use provided in PRVD2019-05.

PMRA in RVD indicated that risk to non-target terrestrial and aquatic organisms were taken into consideration, and referred to Table 16 of PRVD. An examination of Table 16 shows that it was respect to "Aquatic Non-Target Organisms", not terrestrial organisms, and also that the relevant Level of

Concern was exceeded in most instances. This does not address terrestrial organisms, and the findings are generally that the risks are unacceptable because the LOCs are exceeded.

Without specific evidence or analysis on the extent of exposure in the environment for this particular Listed Use, there can not be a certainty of no harm to the environment. The exposure in the environment across Canada for this Listed Use is likely to be extensive, because the use extends to outdoor areas throughout Canada. The EPA in the executive summary of its assessment for chlorpyrifos on endangered species recognizes this point, in stating that:

> "Because of the multitude of uses and use patterns for chlorpyrifos (including mosquito adulticide use), **the action area for chlorpyrifos covers the entire US**, including its territories.
>
> Both the mosquito adulticide and wide area uses are presumed to overlap with all of the listed species ranges and critical habitats because they have no specific geographic footprint." (**Chlorpyrifos Executive Summary for ESA Assessment)** Biological Evaluation Chapters for Chlorpyrifos ESA Assessment | Protecting Endangered Species from Pesticides | US EPA"

Residues on vegetation, surface water and soil last for a long time and provide continued exposure to non-target organisms. When colder nights follow hot days, condensation can deposit residues on these organisms as well. [C A Johansen, *Pesticides and Pollinators*, Annual Review of Entomology 1977 22:1, 177-192]

ii) Second, certain assumptions made and information used by PMRA to come to its conclusion that "there is limited potential for environmental exposure" from this Listed Use are either not plausible or not accurate, or the information is not comprehensive.

One assumption or information put forward by PMRA (RVD p. 21) was that "[p]ollinators are not expected to be present in the evening or at night when chlorpyrifos is applied for mosquito control and beneficial insects are also not expected to be present while foraging during this time". Both pollinators and beneficial insects are discussed below.

Pollinators. It is not the case that there is limited potential for environmental exposure to pollinators for various reasons. One reason is that not all pollinators are inactive in the evening of night. Some bees are "crepuscular", which means they come out at dusk or twilight. [Warrant, Eric J. (June 2008). "Seeing in the dark: vision and visual behaviour in nocturnal bees and wasps". Journal of Experimental Biology. 211 (11): 1737–1746. doi:10.1242/jeb.015396. PMID 18490389.] Crepuscular bees include the bee families known as colletidae, the andrenidae, the halictidae and the apidae [School of Bees, Why Don't Bees Fly at Night?]. All these families are found in Canada.

The Pollinator Stewardship Council (PSC), a national beekeeping organization in the United States notes that honey bees and native pollinators will forage blooming plants until the sun sets, and can be active during dusk, right up till nightfall. Additionally, warm nighttime temperatures and high humidity may induce bee aggregation. [Nichelle Harriet, *Mosquito Control and Pollinator Health*, Pesticides and You, Vol. 36, No. 2, Summer 2016 and the references therein]

Another reason is that chlorpyrifos will come into contact with the soil, and many bees in Canada are "solitary" and nest in soil and in caverns and so will have contact with the chlorpyrifos in the soil. The mining bee is one example. This route of exposure was not examined in the risk assessment. The scientific literature is critical of this lack of examination for this route of exposure, and is calling for assessment with respect to solitary bees, which generally nest underground:

> "Current pesticide risk assessment for bees relies on a single (social) species, the western honey bee, Apis mellifera L. (Hymenoptera: Apidae). However, most of the >20,000 bee species worldwide are solitary. Differences in life history traits between solitary bees (SB) and honey bees (HB) are likely to determine differences in routes and levels of pesticide exposure. ……. Most SB exposure routes seem well covered by current HB risk assessment schemes. Exceptions to this are **exposure routes related to nesting substrates and nesting materials used by SB. Exposure via soil is of particular concern because most SB species nest underground**."[Fabio Sgolastra, Silvia Hinarejos, Theresa L Pitts-Singer, Natalie K Boyle, Timothy Joseph, Johannes Lūckmann, Nigel E Raine, Rajwinder Singh, Neal M Williams, Jordi Bosch, Pesticide Exposure Assessment Paradigm for Solitary Bees, Environmental Entomology, Volume 48, Issue 1, February 2019, Pages 22–35, https://doi.org/10.1093/ee/nvy105]

The route of exposure in the case of solitary bees is as follows:

> "Physical contact between adult bees and toxins on contaminated resources is the simplest and most direct exposure route assessed for solitary bees (Ladurner et al. 2005, Huntzinger et al. 2008a, Biddinger et al. 2015) (Fig. 4). Toxins that contact the bee cuticle may penetrate it directly or may pass (actively or passively) into the body through such orifices as spiracular openings or pores. Besides being directly sprayed during pesticide applications, bees can land on or walk about on contaminated surfaces of soil, lawns, flowers, foliage, or artificial nest materials and even water located in treated fields or gardens. [Routes of Pesticide Exposure in Solitary, Cavity-Nesting Bees Andi M Kopit, Theresa L Pitts-Singer Environmental Entomology, Volume 47, Issue 3, June 2018, Pages 499-510, https://doi.org/10.1093/ee/nvy034]

A recent study from the University of Guelph looked at hoary squash bees, a bee that nests in the ground and is prevalent in Canada. The neonicotinoids examined persisted in soil for longer than a single growing season, and they found "that hazard to ground-nesting hoary squash bees from neonicotinoids in soil (HQsoil = 4.32) is much higher than even the combined hazard from neonicotinoids in both pollen and nectar (HQpollen+nectar = 0.27; Table 1). Therefore, soil appears to be the most important route of exposure to systemic pesticides for hoary squash bees." Although chlorpryrifos is a contact insecticide, the exposure to soil in this study would have been via contact, so there is no reason to differentiate the contact insecticide from the systemic insecticide in this context.

The study found that 93% of the hazard was attributable to soil. They stated: "The combined hazard from insecticides for adult female hoary squash bees from all exposure matrices (soil, pollen, and nectar) was high, with 93% of this hazard attributable to neonicotinoids in soil (Table 1). Hoary squash bees can construct more than one nest per season when environmental conditions (e.g. nectar and pollen resources, weather) permit". [Willis Chan, D.S., Prosser, R.S., Rodríguez-Gil, J.L. et al. Assessment of risk to hoary squash bees (Peponapis pruinosa) and other ground-nesting bees from systemic insecticides in agricultural soil. Sci Rep 9, 11870 (2019). https://doi.org/10.1038/s41598-019-47805-1]

Beneficial Insects. Beneficial arthropods in the area upon which the chemical is sprayed or drifts will come into contact with chlorpyrifos directly, or with plants and the soil on which it lands. It is also the case that some beneficial arthropods forage in the evening, and so would be come into direct contact with the insecticide, meaning that the expectation of PMRA that they would not forage at this time is unfounded. Insects can be active at night because the air temperature is still high, and the temperature of the ground is warm.

Some insects generate their own heat. Insects with big flight muscles are able to warm up their body without sunlight. [When are Bugs most Active during the Day? | Green Pest S(greenpestservices.net).] One example is

the dragonfly, and in cloudy weather and toward evening dragonflies eat mosquitos and can expected to be present during mosquito fogging. [Dragonflies (insectguide.net)]

Birds. With respect to birds, PMRA stated in response to a comment (RVD p.21) as follows:

> "Regarding the risk to flying birds resulting from adult mosquito control, the duration of airborne drift and its rate of dispersal in the atmosphere as well as its deposition rate indicates this exposure is negligible and as such, is not considered by Health Canada. The USEPA (PMRA# 2824701) did state: "Toxicity data are not available for inhalation exposures involving birds; however, in an acute inhalation study with laboratory rats, no mortality was observed at 0.2 mg a.i./mL-air (200 mg/m3) which is equivalent to >5,000 mg a.i./kg bw. Due to a lack of observed toxicity in this study, inhalation exposure is not considered to be of concern…".

Some birds, bats and other species are present in the evening and at night, and it can be expected that those that eat mosquitos will be affected, by either contact or inhalation. The exposure to both would occur during the time when chloryrifos is "suspended in the air long enough to come into contact with mosquitos in flight" (as mentioned in RVD p.21). Because it is designed to be suspended in the air long enough to come into contact with mosquitos, it will presumably be suspended long enough to come into contact with birds and bats in flight that eat mosquitos. The fog remains suspended for a period of time, and is also subject to drift.

Birds that eat mosquitoes include purple martins, swallows, waterfowl (geese, terns, ducks) and migratory songbirds. One example of a bird that would be present during such times is the tree swallow, which The Cornell Lab states: "eat all kinds of flying insects", and "feed from dawn to dusk". Also: "Tree Swallows eat a high insect diet, which through bioaccumulation can expose them to high levels of pesticides and other contaminants such as PCBs and mercury". https://www.allaboutbirds.org/guide/Tree_Swallow/lifehistory#].

PMRA was of the view that exposure to birds through contact would be negligible, and that inhalation exposure was not a concern. The finding on inhalation was based on an EPA study on rats. The EPA did not have data toxicity data for inhalation of bird, and dismissed it based upon a rat study. It stated:

> "Toxicity data are not available for inhalation exposures involving birds; however, in an acute It inhalation study with laboratory rats, no mortality was observed at 0.2 mg a.i./mL-air (200 mg/m^3) (MRID 00146507) which is equivalent to >5,000 mg a.i./kg bw . Due to a lack of observed toxicity in this study, inhalation exposure is not considered to be of concern for this analysis."

One concern with this dismissal is that it was based upon a confidential study from 1984 that was not available for inspection. It is likely that the rat study utilized "nostril" methodology, which is not appropriate with respect to birds.

A second concern is that the dismissal was not warranted or justifiable, for the simple reason that birds breathe differently than mammals and so the rate was not representative of the bird for the purposes of making findings on inhalation: "Unlike in mammals, air flows in only one direction through bird lungs" (http://people.eku.edu/ritchisong/birdrespiration.html). This makes them more sensitive to harm from inhaled toxins.

A Harvard study that looked at this issue indicated that intoxification from some inhaled substances occurred sooner with birds than other animals and prior to the development of potentially lethal pathology in other animals. (p. 197 R E Brown, J D Brain, N Wang, *The avian respiratory system: a unique model for studies of respiratory toxicosis and for monitoring air quality* PMID: 9105794 PMCID: PMC1469784 DOI: 10.1289/ehp.97105188) The "evolutionary process" of birds "has produced a respiratory system with substantial physiological differences relatives to the comparable features of other vertebrates." They indicate that "much of the birds' respiratory system appear to lack any of the clearance mechanisms attributed with maintaining respiratory homeostasis and health in mammals" (p. 198) and that they are more susceptible to toxicosis through respiration.

Similar studies show that birds, as compare to mammals, experience greater respiratory stress, such as this one that compared chickens to rats: [S G Kiama, J S Adekunle, and J N Maina J Anat. 2008 Oct; 213(4): 452–463. *Comparative in vitro study of interactions between particles and respiratory surface macrophages, erythrocytes, and epithelial cells of the chicken and the rat,* Published online 2008 Jul 14. doi: 10.1111/j.1469-7580.2008.00951.x PMCID: PMC2644778 PMID: 18643797]. Based on the fact that birds breathe differently than rats are more susceptible to toxins, as evidence by the above studies and similar supporting scientific knowledge, the PMRA finding that inhalation exposure for birds is not of concern based upon the findings of a study on rats is unfounded.

The exposure to birds occurs via multiple routes, more than just inhalation. The EPA has found that chorpyrifos is very highly toxic via the oral route to birds when it simulated exposure. [Details: quote on birds:)(p. B7(ED) – 3)United States Environmental Protection Agency (U.S.EPA), 2016e, Biological Evaluation Chapters for Chlorpyrifos ESA Assessment, Appendix 4-7. Refined risk analysis for 13 listed birds exposed to chlorpyrifos, 18 pp, https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment, DACO: 12.5.9):

> **"2.3 Exposure routes simulated**
>
> TIM has the ability to account for exposures via multiple routes, including diet, drinking water, dermal and inhalation. Acute oral toxicity data with birds indicate that chlorpyrifos is very highly toxic via the oral route (chapter 2). This suggests that dietary and drinking water routes are potentially of concern.

Appendix 4-3d of Biological Evaluation Chapters for Chlorpyrifos ESA Assessment | Protecting Endangered Species from Pesticides | US EPA shows that birds are exposed to high risk from chlorpryrifos.

Drinking water for birds would include sources in the "temporary pools – standing water" use discussed above, and also sources of water upon which the adultcide lands. Food sources for birds would also be affected by the fog.

Bats: The information used by PMRA to come to the conclusion that there was limited potential for environmental exposure from this Listed Use was not comprehensive. Bats and other predators of mosquitos feed on mosquitos at dusk, but the PMRA did not examine the exposure to bats for this Listed Use. With respect to bats. Bats consume 3,000 or more mosquitoes and other insects every night, according to Nature Canada. Chlorpyrifos has sublethal and harmful effects on bats. [Eidels, R.R., Sparks, D.W., Whitaker, J.O. et al. Sub-lethal Effects of Chlorpyrifos on Big Brown Bats (Eptesicus fuscus). Arch Environ Contam Toxicol 71, 322–335 (2016). https://doi.org/10.1007/s00244-016-0307-3]

Other predators: Other predators of mosquitos will also be affected and were not considered by PMRA.

Examples are the dragonfly and the damselfly. Dragonflies and damselflies both eat mosquitos, so can be expected to be present when fogging for mosquito occurs. The EPA assessment of chlorpyrifos on damselflies and dragonflies show high risk: See Appendix4-3f Endangered Species in invertebrates of Biological Evaluation Chapters for Chlorpyrifos ESA Assessment | Protecting Endangered Species from Pesticides | US EPA.

Resistance and Other Predators. An article in the Journal of the American Mosquito Control Association referenced a study that showed that long-range effects of pesticide spraying can actually increase the number of mosquitoes by destroying their natural predators.

> "A 1997 study looked at trends in populations of a mosquito primarily responsible for transmitting eastern equine encephalitis (EEE) among birds. Over a period of eleven years, Cicero Swamp in central New York State was sprayed fifteen times with the insecticide Dibrom (naled). Instead of declining, the mosquito population grew fifteen-fold during this period. The study suggests that the pesticides may have altered the ecological balance of the swamp, killing organisms whose presence would ordinarily help limit the mosquito population." [Oliver Howard, "Impact of naled (Dibrom 14) on the mosquito vectors of eastern equine encephalitis virus," Journal of the Am Mosquito Control Assoc, Dec; 13(4):315-25, 1997].

This phenomenon of mosquitos adapting resilience in areas of insecticide spraying was discussed in a 2019 study, which compared mosquitos to damselflies. The authors found "that the ability to evolve resistance to an anthropogenic stressor has allowed W. abebala to not only colonize new ecosystems, but ecosystems that do not contain their most common predator and are also potentially less susceptible to natural stressors". [Jennifer Weathered1 · Edd Hammill Adaptation to agricultural pesticides may allow mosquitoes to avoid predators and colonize novel ecosystems Oecologia (2019) 190:219–227 https://doi.org/10.1007/s00442-019-04403-2]

iii) Mitigation Measure Still Presents Unacceptable Risks. A further concern with the evaluation for the Listed Use of adult mosquito control is that the required mitigation measure still present unacceptable risks. Although PMRA spoke to spraying with "ULV" applications of "ASABE" droplets, the label amendments as set out in Appendix V of RVD do no mandate such applications.

The mitigation measure of specifying site characteristics on labels is problematic, because it is based on information that is questionable. These "site characteristics" was not subjected to an exposure assessment, so it is not known the extent to which or whether they mitigate the risk of exposure to non-target organisms.

It is also not clear how the "site characteristics" will "intercept" chlorpyrifos and stop it from hitting the ground or groundwater, and no explanation was provided for this remarkable phenomenon of "interception". Chlorpyrifos is said to settle on the surfaces of "cryptic habitat" such as the undersides of leaves, vegetation and structures that are in the "sites" of shallow, grassy depressions; industrial parks; roadway ditches; railway marshalling yards; small temporary sloughs and flooded woodlands.

Despite the pronouncement of PMRA, it cannot be said with any certainty that the surfaces of the "cryptic habits" found in shallow, grassy depressions, industrial parks, roadway ditches; railway marshalling yards; small temporary sloughs; and flooded woodlands will to any large degree "intercept" or stand in between the settling chlorpyrifos fog and the ground or water that is on these sites.

Moreover, terrestrial species will still come into contact with the "cryptic habitat" and be exposed. PMRA already stated in RVD 2020 (p.2) that there are environmental risks of concern to beneficial arthropods, birds, mammals and all aquatic biota from chlorpyrifos. Reliance on the mitigation measure of "site characteristics" to mitigate the risk from fogging for adult mosquitos does not provide a certainty that is reasonable, ie. that has evidence to support it, that there will not be environmental risks of concern to beneficial arthropods, birds, mammals and all aquatic biota arising from this Listed Use.

iv) Finally, there are concerns with the assessment of value for the use of chlorpyrifos for adult mosquito control. PMRA did not provide any proposition of value for this Listed Use, in either of the Evaluations.

PMRA does state in the value assessment and the Conclusion of the Science Evaluation on Value that "Alternative products to chlorpyrifos are available for use as a fog to control adult mosquitoes". Because PMRA speaks in the "value" section on the proposed uses, it is presumed that the meaning of "fog control" in the value discussion is the "cold fogging" using ULV spraying referenced above. Thus there are alternatives to using chlorpyrifos for fogging.

Because alternatives are available, the value proposition for using chlorpyrifos for this use is not strong. As indicated, one goal of the pest control regime is to encourage the development and use of alternative, non-toxic, ecological pest control approaches, strategies and products. Although PMRA does not provide the identity of the alternatives to chlorpyrifos for this Listed Use, it is likely that they are less toxic and dangerous than chlorpyrifos, since most outdoor uses of chlorpyrifos pose unacceptable risks, the chemical is toxic, moderately persistent if not persistent (as will be discussed), and meets at least one criteria for bioaccumulation. It is hard to understand the value proposition for using a toxic and otherwise dangerous pesticide, when less toxic alternatives exist that better protect the environment.

In a re-evaluation, alternatives are to be taken into account, including nonchemical alternatives. "During re-evaluation, value is examined under current conditions and in light of alternative pest control methods (both chemical and nonchemical) that may have been developed since the pesticide was first registered." (PMRA's Decision Framework SPN2000-01 p. 12)

There is no value to using chlorpyrifos for outdoor mosquito control, nor will there be future value when viewed from the perspective of the PCPAct that requires a certainty that is reasonable that there is "no harm" to future generations. The reason is that the efficacy of fogging for adult mosquito control with ULV sprayers is very low. As mentioned, PMRA in the DIR2013-03 Value Assessment has directed that pesticide products should have a level of efficacy that significantly contributes to pest management in order to be registered in Canada.

The above referenced article "Mosquito Control and Pollinator Health" provide the explanation and scientific backup:

> "[B]ecause the ULV spray can only kill mosquitoes that the fine particles come into contact with, the number of which may be limited (one study notes that less than 0.0001% of the insecticide reaches the target mosquitoes),6 this method is not an effective long-term strategy to effectively control mosquito populations. The efficacy of ULV spraying also depends on time of day applied, and weather factors, such as wind velocity and direction, temperature, and atmospheric stability and turbulence.7" [Referenced articles: 6: Pimentel, D. 2004. West Nile Virus and Mosquito Control. Encyclopedia of Pest Management. doi: 10.1081/E-EPM 120009995; 7: Mount, GA. 1998. A critical

review of ultralow-volume aerosols of insecticide applied with vehicle-mounted generators for adult mosquito control. J Am Mosq Control Assoc. 14(3):305-3]

The Pimentel article referenced provides further explanation and scientific evidence to show the lack of efficacy of using ULV sprayers:

> "The insecticide spray produced from these [ULV] units is like a smoke or fine mist and is carried downwind. Even assuming that the spraying is carried out in the evening when wind is minimal, the spray is carried downwind in an open area, for instance, on a golf course. Downwind, from 150 to 300 ft and at 3 ft height, the mosquito kill will range from 25% to 75%.[5] However, ZERO mosquitoes will be killed upwind by the insecticide spray. Thus the average upwind and downwind kill is only 21% to 45%. Note, the insecticide spray does not penetrate buildings, and mosquitoes behind buildings are not killed. Further, dense vegetation hinders spray treatment and desired mosquito control. For example, downwind in a dense stand of trees, mosquito kill is reported to be only 34% to 58%.[5]….
>
> For effective mosquito control, at least 90% of the adults must be killed. Only a few scientific studies of the effectiveness of spraying for mosquito control have been reported. These results are relatively discouraging. For example, in Greenwich, CT, only a 34% mosquito population reduction was reported after ground spraying, and in Houston, TX, only a 30% reduction occurred after spraying.[6] Then in Cicero Swamp, FL, populations of disease-carrying mosquito populations increased 15-fold after spraying,[6] when the mosquito population was measured 11 days after spraying. However, it is doubtful that the insecticide spray caused the increase in the mosquito population, but clearly the insecticide provided insufficient adult mosquito control." (David Pimentel, "West Nile Virus and Mosquito Control" Cornell University, Ithaca, New York, U.S.A.) [6] = Outcome. Outcome Studies: Control Efforts for West Nile Virus and Mosquito Population; 2003. http://www.ccheinfo.com/pdf/cche-wnv_outcome_studies.pdf (8/13/03)

Interestingly, the very "cryptic habitats" promulgated by PMRA can actually reduce the efficacy of ULV sprayers because they shelter the mosquitos, as explained in the follow review:

> "Failures in mosquito adulticiding often occur because of an over simplification of the system within which we work. Where the target area is open and with few obstacles obstructing air flow specifically from ground applications, control is usually achieved. However, mosquitoes prefer to reside in a harborage, often in a plant canopy or a residence. The target, therefore, is the porous vegetative media between the air aloft and the ground. The obstacles can filter out the spray and shelter the mosquitoes from direct impact with the spray". [J.A.S. Bonds, Ultra-low-volume space sprays in mosquito control: a critical review, Medical and Veterinary Entomology (2012) 26, 121-130 doi/full/10.1111/j.1365-2915.2011.00992.x]

Weather and metereology also impact efficacy. Wind can cause the fog to drift, and the potential for drift is high during temperature inversions.

Edmonton and Winnipeg have been two of the municipalities in Canada most concerned about mosquito control. With respect to this Listed Use, Edmonton discontinued fogging of the river valley and ravine system in 1993 (link: here), and the webpage of the City of Winnipeg indicates that Winnipeg uses DeltaGard® (Deltamethrin) for this use (link: here), not chlorpyrifos.

In summary, PMRA does not provide a proposition for value of the Listed Use of chlorpyrifos for adult mosquito control, there are alternatives, the efficacy is extremely low and meaning chlorpyrifos does

not “significantly contribute” to pest management, and chlorpyrifos apparently is not being used in Canada for adult mosquito control as it once was.

C. Objections Re: Listed Use: Structural indoor and outdoor (non-residential).

PMRA in PACR 2003-03 describes this Listed Use (p. 31) as: “Uses inside and outside commercial buildings where there is limited access by the general public”, and that “[t]his includes warehouses, railroad boxcars and industrial Plants”. *The PMRA Guidance Document, Structural Pest Control Products: Label Updates* states: “Non-residential structures include, but are not limited to, industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, cargo areas, railcars); **animal housing (for example, livestock housing, pet kennels**); and **areas within specific residential structures** where the general public, including children, will have no access such as furnace rooms, storage areas in multi-unit dwellings, etc.”

When discussing the fate and behaviour of chlorpyrifos with respect to the use in and around structures (and mosquito control), PMRA indicated (p. 5 PRVD) that “environmentally-relevant concentrations are not expected from these uses when used according to label directions”. And at p. 25 it stated: “Risk from ….. indoor and outdoor structural, adult and larval mosquito uses of chlorpyrifos are acceptable from an environmental perspective.” The conclusion of the science evaluation was (p. 27 of PRVD): “Greenhouse ornamental, outdoor ornamentals (container stock only) for control of Japanese beetle larvae, indoor and outdoor structural, adult and larval mosquito uses of chlorpyrifos are considered to be acceptable from the environmental perspective **due to the limited potential for environmental exposure**.”

The concerns with these evaluations on the Listed Use for chlorpyrifos on structures (indoor and outdoor) are the following:

i) Again, PMRA did not assess the exposure to the environment from this use, representing a failure in approach and methodology. It indicated that environmentally-relevant concentrations “are not expected” and that there is limited potential for environmental exposure, without providing evidence or analysis for this.

The behaviour and fate of chlorpyrifos, as shown by the science, is that it will volatize into the air and be subject to condensation and long-range transport, and also sorb to soil such that with rainfall it can enter surface water. The harms to the environment because of such behaviour and fate have been documented, and are such that PMRA saw fit to “cancel most outdoor uses of chlorpyrifos due to environmental risks of concern (risks to beneficial arthropods, birds, mammals and all aquatic biota)” (RVD p.2).

ii) There are problems with the assumptions made and the lack of evidence to support them. It is not the case that the potential for environmental (and human health) exposure is limited, just because the applications are limited to non-residential structures. It should be noted that that broadcast treatment of the chemical is permitted with this use. Broadcast treatment is permitted on the outdoor perimiter and exterior surface of structures, and this **means the chemical will land on and sorb to soil** and “can enter surface water through runoff as surface soil particles are dislodged due to rainfall”.

Outdoors. Outdoor broadcast treatment will present risks similar to those presented in the discussion on outdoor mosquito use. The chemical will get into soil, onto foliage, and into air, and various species in the environment will be exposed, including beneficial arthropods, mammals, birds and others through direct contact, diet, inhalation or dermal contact.

Indoors. Broadcast surface spray is permitted in the indoor use as well, which means it will volatize into the indoor air and be subject to inhalation, and land on items located indoors. Scientific studies show that air concentrations of chlorpyrifos peak at a time that is well after broadcast treatment, and that substantial redistribution of chlorpyrifos from treated to untreated surface areas can occur in the first 24 hours after application [Fenske RA, Black KG, Elkner KP, Lee C, Methner MM, Soto R. Potential exposure and health risks of infants following outdoor residential pesticide applications. Am J Public Health 80:689-693 (1990). 5. Fenske RA, Curry PB, Wandelmaier F, Ritter L. Development of dermal and respiratory sampling procedures for human exposures to pesticides in indoor environment. J Expo Anal Care Environ Epidemiol 1:11-30 (1991).]

A 1998 study by the Environmental and Occupational Health Sciences Institute ("EOHSI") of Rutgers University [Gurunathan S, Robson M, Freeman N, Buckley B, Roy A, Meyer R, Bukowski J, Lioy PJ. Accumulation of chlorpyrifos on residential surfaces and toys accessible to children. Environ Health Perspect 106:9-16 (1998)] showed that "chlorpyrifos does not dissipate or settle down when deposited in the particle phase. Chlorpyrifos, like many semivolatile pesticides that are applied as pressurized sprays, functions both as an aerosolized particle and as a gaseous compound. After initial deposition, the compound vaporizes into the gas phase 12 hr after spraying and is airborne, at which time it becomes absorbed onto various solid surface areas, including furniture and children's toys. The EOHSI study demonstrated that the compound continued to be released into the gas phase and became deposited on a variety of solid surfaces for at least 2 weeks after a single broadcast application." (Described in Devra Lee Davis and A. Karim Ahmed, *Exposures from Indoor Spraying of Chlorpyrifos Pose Greater Health Risks to Children than Currently Estimated* Environmental Health Perspectives, Volume 106, Number 6, June 1998 299).

PMRA provides a very broad definition of a structure and explains residential and non-residential structures in *PMRA Guidance Document Structural Pest Control Products: Label Updates 28 February 2020* p.2 as follows:

> "A structure can be a building or non-building to which a pesticide may be applied. Buildings are considered as any structure used or intended for supporting or sheltering any use or occupancy (NRC, 2015). Types of buildings include but are not limited to homes, schools, offices, animal housing, greenhouses and mushroom houses, factories, food and non-food storage facilities and food processing facilities. Non-buildings are those that are not designed for continuous human or domestic animal occupancy. Types of non-buildings include but are not limited to parking structures, roads/driveways, perimeter barriers such as fences or retaining walls, utilities (such as sewers, drains, telephone poles), patios and decks.
>
> A residential structure is one where the general public, including children, could be exposed during or after application. Residential structures include, but are not limited to, homes, garages, schools, restaurants, hotels/motels, public buildings or any other structures where the general public including children may potentially be exposed. Non-residential structures include, but are not limited to, industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, cargo areas, railcars); animal housing (for example, livestock housing, pet kennels);

and areas within specific residential structures where the general public, including children, will have no access such as furnace rooms, storage areas in multi-unit dwellings, etc."

The concern is that people will be exposed to chlorpyrifos by virtue of this Listed Use. The fact that the general public has "limited access" to "non-residential" structures does not mean that there will not be access by individual people to the structures. In fact, some of the structures, such as "industrial plants" and "areas within specific residential structures", can be expected to contain individual people for long periods of time. By way of example, the Listed Use is allowed inside food processing plants and meat packing plants (p.40 REV2007-01), where many people work. Further, some of the structures include food granaries, animal housing, and food processing plants, which means food will likely be exposed to chlorpyrifos. The risk of exposure to individual people who are present in or around non-residential structures and of exposure to food is exacerbated by the fact that there are no timing restrictions with respect to application (p.12 PRVD).

Statistics Canada provided statistics on the number of employees employed in different sectors in Canada, in its report Table 14-10-0108-01 *Employment by class of worker and industry, annual, population centres and rural areas*, inactive (x 1,000) DOI: https://doi.org/10.25318/1410010801-eng (archived). The last year reported on was 2017. In that year, the total employed in all industries classified under the NAICS system was 18,416,400. The total employed in all industries except for industries that we liberally estimated the general public would access, or that are likely performed substantially outside, was 10,729,999. The excepted categories were (x1000): Agriculture (279.5); Forestry, fishing, mining, quarrying, oil and gas (329.6); Construction (1,409.3); Educational Services (1,285); Health care and social assistance (2,383.2); Information, culture and recreation (789.3); and Accommodation and food services (1,210.8). These excepted categories are overly liberal, because the exceptions include workers in structures that are "modes of transport in areas where passengers are not present", and do not include "areas within specific residential structures where the general public, including children, will have no access".

The Statistic Canada numbers reveal that in 2017 there was in theory the potential for over 10 million employees (not including self-employed people) in Canada to work in settings in which chlorpyrifos can be sprayed. By extrapolation from the numbers for the total population in Canada in 2017 (36.54 million) to 2020 (37.74 million), this equates to 11,082,372 in 2020 numbers.

There is also a risk to animals, because "structures" include "animal housing (for example, livestock housing, pet kennels)". Domesticated animals are harmed by chlorpyrifos. By way of example, the chemical is highly toxic to chickens, and chickens undergo respiratory stress from exposure to chlorpyrifos [S G Kiama, J S Adekunle, and J N Maina J Anat. 2008 Oct; 213(4): 452–463. *Comparative in vitro study of interactions between particles and respiratory surface macrophages, erythrocytes, and epithelial cells of the chicken and the rat,* Published online 2008 Jul 14. doi: 10.1111/j.1469-7580.2008.00951.x PMCID: PMC2644778 PMID: 18643797.]

Health Canada, in *Information Note: Assessing Human Health Risks During Pesticide Review in Canada* indicates that "As part of its assessments, the PMRA estimates the amount of exposure to which a user **and bystander(s**) could be exposed through use of the product. A pesticide will only be approved if this estimated exposure raises no concern", and "A pesticide will only be approved if this estimated exposure raises no concerns." The fact that PMRA has decided to separate the assessment from human health from the assessment on the environment does not mean that an assessment of the exposure to humans from the use of chlorpyrifos on non-residential structures is not required.

It is expected that such an assessment will be included in the update to the human health risk assessment that will be presented in a future document (p.3 RVD) This expectation is buttressed by the point that the pest control regime does not contemplate separating the assessments of health risk, environmental risk and value: a notice of objection under Section 3 of the *Review Panel Regulations* speaks to the to: "the evaluations, on which the decision was based, of the health **and** environmental risks **and** the value of the pest control product."

Risks to the environment and health often overlap. Because the assessments are separated, there is room for relevant considerations to "fall through the cracks"; such as the case in point, the assessment of human health risks arising from structural use. The separation of the assessments is also burdensome on the participatory process, because any objections concerning risks arising in the areas of overlap must be raised in relation to the decisions on both the environment and health publications, to ensure they are considered. Moreover, under Section 17.1 of the PCPAct the "ongoing" risk assessment process utilized by PMRA on this file allows it to delay any special review on the substance triggered under the PCPAct Section 17 (2) "when a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons". Member states of the European Commission voted to ban chlorpyrifos in 2019.

With respect to the update on the human health risk assessment, it is expected that comments will be accepted to the health assessment. Many Canadians have concerns with the health risks associated with chlorpyrifos given the evidence not only that the chemical affects children, but also that it significantly contributes to Multiple Chemical Sensitivity or "MCS" and other ailments. [Ziem G, McTamney J. Profile of patients with chemical injury and sensitivity. Environ Health Perspect. 1997 Mar;105(Suppl 2):417–36.]

PMRA in RVD required in the label amendments that labels should be consistent with the PMRA Guidance document, Structural Pest Control Products: Label Updates (**"Structure Guidance Document"**). No other amendments with respect to the use on or in structures was made. The registered uses set out in Appendix II of PRVD 2019 p. 38 include for use outdoors:"Exterior perimeter, broadcast treatment and spot treatment", and for use indoors: "crack and crevice and spot treatment, and Broadcast surface and crack and crevice spray". The Structure Guidance Document provides definitions for indoor and outdoor broadcast as set out below. The broadcast applications contemplate "large outdoor structural surfaces" outdoors, and "broad expanses of indoor structural surfaces" indoors.

Application Type	Definition
Outdoor Structural Broadcast2	Outdoor broadcast application is to large outdoor structural surfaces (roofs, walls, doors, windows and foundations).
Outdoor Perimeter3,4	Outdoor perimeter application is 1 m or less out from the building's foundation and to a maximum height of 1 m starting where the foundation meets the ground.
Indoor Broadcast	Indoor broadcast application is to broad expanses of indoor structural surfaces such as walls, floors, ceilings and indoor foundation walls/crawlspaces.

Given the expansive areas considered for broadcast spraying, it can be expected that the concentrations of chlorpyrifos that will be distributed to the environment and into structures that humans inhabit will be "environmentally relevant" and also relevant from a human health perspective.

iii) There are concerns with the assessment of value for the Listed Use on structures. The main concern is that alternatives exist for both indoor and outdoor use, and less toxic alternatives are to be encouraged under the pest control product regime. For indoor non-residential use, PMRA is clear product alternatives exist (PRVD p. 26 and 28). Although PMRA did not name the alternatives, as stated above, they are likely less dangerous than chlorpyrifos. For outdoor non-residential use, PMRA indicates that there are a number of alternatives registered for use, although the number is limited. (PRVD 26). The implication is that there are alternatives for outdoor use that have not been registered. By way of example, neem oil has not been registered in Canada, and it is effective against many bugs.

These alternatives are to be taken into account as well because "During re-evaluation, value is examined under current conditions and in light of alternative pest control methods (both chemical and nonchemical) that may have been developed since the pesticide was first registered." (PMRA's Decision Framework SPN2000-01 p. 12) If the reason for lack of registration is that the chemical manufacturer does not envision a viable economic proposition that justifies the registration effort, the alternative could be registered under a URMULE application. If the reason for lack of registration is that the alternative is commonly available (e.g., cooking oil, soap, rubbing alcohol, cayenne pepper, certain plants that attract beneficial insects or repel pests) it is submitted that these alternative nonchemical pest control methods still warrant consideration.

D. Objections Re: Listed Use: Elm bark beetle and mountain pine beetle control.

With respect to this use, PMRA states (p.8 of RVD):

> "Since the publication of PRVD 2019-05, Health Canada has determined that the environmental exposure of chlorpyrifos use for elm bark beetle and mountain **pine beetle control is expected to be low**, because chlorpyrifos is directly applied to the lower portion of the tree trunk and is not broadcast into the surrounding environment….. These uses are now considered to pose acceptable risks to the environment and will be retained. Inhalation exposure is not considered an environmental concern according to the USEPA (PMRA# 2824701). These uses are now considered to pose acceptable risks to the environment and will be retained."

The label amendments set out in Appendix V of RVD indicate the acceptable uses include "Tree trunk applications to control elm bark beetle and mountain pine beetle".

In PACR 20003-02 PMRA indicated that as of 2003 this use for control of the elm bark beetle was supported by research in Winnipeg (p.32):

> "Dutch elm disease
>
> Chlorpyrifos has been registered as a general foliar spray and as a treatment to the bark of elm trees to control elm bark beetle, which is a carrier of the causal fungus of Dutch elm disease. **Research in Winnipeg has shown that the treatment can be limited to one fifth of**

> **the currently labelled application rate, i.e., application to a 0.5 m band at the base of the trunk.** Labelling will therefore reflect this reduced application rate and method of application. This treatment is currently used only in prairie towns and cities where the American elm is the principal shade tree and is under the authorization of the provinces".

The concerns with these evaluation by PMRA on this Listed Use for Elm Bark Beetle and Mountain Pine Beetle Control the following:

i) First, PMRA did not assess the exposure to the environment from this use. The concentrations of chlorpyrifos entering the atmosphere and soil and groundwater were not assessed. Based on the known fate and behavior of the chemical, there is the potential for it vaporize, and also to be washed off the base of the tree and sorb to soil, and enter surface water from there.

ii) Second there are concerns with the finding that "Inhalation exposure is not considered an environmental concern according to the USEPA (PMRA# 2824701)" which is used to support the conclusion that "environmental exposure … is expected to be low". The particular USEPA Document in issue is the document discussed earlier, that was described at p.21 of RVD in discussing inhalation exposure to **birds** in the use of adult mosquito control. It stated:

> "The USEPA (PMRA# 2824701) did state: "Toxicity data are not available for inhalation exposures involving birds; however, in an acute inhalation study with laboratory rats, no mortality was observed at 0.2 mg a.i./mL-air (200 mg/m3) which is equivalent to >5,000 mg a.i./kg bw. Due to a lack of observed toxicity in this study, inhalation exposure is not considered to be of concern…".

The EPA named the rat study as MRID 00146507, cited as "Hardy, C.; Jackson, G. (1984) Dursban Technical: Acute Inhalation Toxicity in Rats: Report No. DWC 411/84774. Unpublished study prepared by Huntingdon Research Centre, plc. 23 p." (p. B7(ED) – 3) United States Environmental Protection Agency (U.S.EPA), 2016e, Biological Evaluation Chapters for Chlorpyrifos ESA Assessment, Appendix 4-7. Refined risk analysis for 13 listed birds exposed to chlorpyrifos, 18 pp, https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment, DACO: 12.5.9). This study is unpublished, so cannot be viewed for purposes of transparency.

However, the National Pesticide Information Centre considers chlorpyrifos to be **moderately toxic**, based upon rat studies, which contradicts the finding of a lack of observed toxicity in rats apparently found in the EPA study. [Reference: http://npic.orst.edu/factsheets/archive/chlorptech.html#references] The rat studies were performed later than the 1984 EPA study. The Centre states: "Chlorpyrifos is considered **moderately toxic by inhalation**. The 4- to 6-hour LC50 is >0.2 mg/L in rats." [The references provided for this statement were: 1. Tomlin, C. D. S. The Pesticide Manual, A World Compendium, 14th ed.; British Crop Protection Council: Alton, Hampshire, UK, 2006; p 186-187; and 2. Kamrin, M. A. Pesticide Profiles Toxicity, Environmental Impact, and Fate; Lewis Publishers: Boca Raton, FL, 1997; pp 147- 152].

iii) Third, there are concerns with the misapplication of the scientific data presented. The "Winnipeg study" indicated that for the elm bark beetle, application could be limited to a 0.5 metre at the base of the trunk. PMRA apparently considers that this information is applicable and appropriate for the mountain pine beetle as well, when it states (p 8. RVD) that "Health Canada has determined that the environmental exposure of chlorpyrifos use for elm bark beetle **and mountain pine beetle control is**

expected to be low, because chlorpyrifos **is directly applied to the lower portion of the tree trunk** and is not broadcast into the surrounding environment".

However, the behaviour of the mountain pine beetle is such that spraying at the very bottom of the tree trunk (0.5 metres) will not be effective. The reason for the application at the bottom of the trunk for the elm bark beetle ("**EBB**") is that this the location where adult EBBs locate to overwinter. The snow insulates this area of the tree during that time. The life cycle of the EBB is that the eggs are laid in dead or dying elm trees, they emerge in the Spring, fly to healthy trees in the summer and mate, and then the female bores into the cambian layer of the tree, which is the area of the tree that transports the water and nutrients that is located inches below the bark. If the beetles are carrying elm bark disease, this is also the area where the spores of the disease spread, which block the conduction of water for the tree with the result that the tree dies. [Irene Pines and Richard Westwood, *"A Mark-recpature Technique for the Dutch Elm Disease Vector theh Native Elm Bank Beetle, Hylurgopinus rufipes (Coleoptera: Scolytidae)* , Arboriculture & Urban Foretry 2008. 34(2): 116-122]. Insecticides are applied to the base of the tree in the last weeks of September, with the purpose of killing them as they enter the base of the tree to overwinter. [S. OGHIAKHE AND N. J. HOLLIDAY, *Evaluation of Insecticides for Control of Overwintering Hylurgopinus rufipes (Coleoptera: Curculionidae*) JOURNAL OF ECONOMIC ENTOMOLOGY Vol. 104, no. 3 p.892]

In contrast, the life cycle of the mountain pine beetle ("**MPB**") is such that it does not bore into the base of trees in order to overwinter. Rather, all of the life stages or the MPB occur below the bark, except for when it emerges to attack trees [U.S. Dept. of Agriculture: Forest Insect & Disease Leaflet 2 Mountain Pine Beetle Reprinted 1990]. It emerges from locations all along the trunk of the tree, not just from the bottom section, and, as a result, spraying of the entire trunk is needed.

This is consistent with the label directions set out in PMRA's Re-evaluation Note 2007-01 *Update on the re-evaluation of Chlorpyrifos*, which addressed comments on PACR2003-03 and put in place interim mitigation measure to further protect workers and the environment. The label directions were to spray to a height of "at least" 3 metres: "Treat boles from ground level up to a height of at least 3 m or until a bole diameter of 12.5 cm is reached". The Colorado State Forest Service provides similar direction for spraying the MPB in its publication *Preventive Spraying for Mountain Pine Beetle:* Information Services, MPB #2 (p. 2):

> "Preventive spray is applied to the trunk from the ground up to a height of 30 feet OR where the trunk narrows to 6 inches, whichever comes first. For example, if a tree trunk narrows to 6 inches at a height of 22 feet, only the lower 22 feet of trunk need spraying. In contrast, if another tree narrows to 6 inches at a height of 54 feet, only the lower 30 feet of trunk needs spraying. Spraying should wet the bark, but only to the point of run-off. To adequately spray a typical, large pine takes about 2-4 gallons of spray mixture. The entire circumference must be treated. Pine foliage and branches under 6" in diameter do not need to be sprayed**".**

iv) Finally, there are concerns with the assessment of value. As stated, pesticide products should have a level of efficacy that significantly contributes to pest management (2013 Value Directive). Chlorpyrifos does not contribute to management of the mountain pine beetle. The reason is that the mountain pine beetle problem has reached epidemic levels for many reasons, including that summers have become more hot, as reported by Natural Resources Canada:

> Normally these insects [mountain pine beetles] play an important role in the life of a forest. They attack old or weakened trees, speeding the development of a younger forest. However,

> unusual hot, dry summers and mild winters in central British Columbia during the last few years, along with forests filled with mature lodgepole pine, have lead to an epidemic. [https://web.archive.org/web/20100811062345/http://mpb.cfs.nrcan.gc.ca/biology/index_e.html]

Once an infestation of a forest has occurred, insecticide use is not effective again the MPB [Amalesh Dhar, Lael Parrott, and Christopher D.B. Hawkins, *Aftermath of Mountain Pine Beetle Outbreak in British Columbia: Stand Dynamics, Management Response and Ecosystem Resilience*, Forests https://www.mdpi.com/1999-4907/7/8/171/pdf] In the situation of the MPB, insecticides are generally use only as single tree treatments, for preventive measures. They do not contribute significantly to management of the MPB. For example, the only insecticide Alberta uses it uses carbaryl (trade name Sevin) to protect high value trees, such as those in campgrounds or other landscaped sites, from MPB. [Mountain Pine Beetle Management Strategy (alberta.ca)]

With respect to the elm bark beetle, there are alternatives available. Two such registered alternatives are permethrin (as a stop gap measure) and bifenthrin [OGHIAKHE AND HOLLIDAY: INSECTICIDES FOR OVERWINTERING *H. rufipes* JOURNAL OF ECONOMIC ENTOMOLOGY Vol. 104, no. 3 p. 893]. Bifenthrin is less toxic than chlorpyrifos, in that it has low toxicity for mammals, and so its risks are more acceptable than those of chlorpyrifos, making it the preferred alternative.

Alternative and more effective pest control strategies for the elm bark beetle include establishing buffer zones, sanitation plus rapid removal. Rapid removal is based on the research conducted in the City of Winnipeg: "This research also found a small percentage of diseased elm trees contained very large amounts of elm bark beetle brood…. This study revealed that with five years of a rapid removal regimen, the incidence of DED was cut by half as the beetle populations were reduced significantly over that time." [City of Winnipeg, *Dutch Elm Disease Research*]

E. Objections re Toxic Substances Management Policy Considerations.

The PMRA in PRVD2019 (p.26-27) concluded that chlorpyrifos does not meet all Track 1 criteria, and is not considered a Track 1 substance. Appendix III, Table 40 in support. The table indicated with respect to persistence that the half-life threshold was not met, but that there was evidence of long range transport. With respect to bioaccumulation, the Table indicated the BAF was not met, but that the Log KOW threshold was met. With respect to the BCF, it stated "weight of evidence indicates not Tract 1 (Table 12)."

i) One objection is that with respect to persistence, PMRA in an earlier statement, PACR 2003-03, indicated chlorpyrifos was persistent. The European Chemicals Agency in its Stockholm Proposal (p.10) found that chlorpyrifos fulfilled the criteria for persistence. This raises concerns with the information or weight of evidence approach used by PMRA on persistence in PRVD 2019.

ii) The second objection is with respect to BCF. The ECHA in its Stockholm Proposal (p. 15) found:

> The BCF of 5000 is exceeded for plants and early life stages of fish. Additionally, the log kow for chlorpyrifos is greater than five. We therefore conclude that chlorpyrifos meets the annex D c I criteria for bioaccumulation.
>
> Although numerous BCF, being below 2000, show moderate bioconcentration, this in combination with high toxicity especially to sensitive life stages gives reason for serious concern.

> A BSAF of up to 99 suggest a high bioaccumulation in sediment dwelling organisms. We therefore conclude that chlorpyrifos meets the annex D c II criteria for high toxicity and ecotoxicity.

The *Persistence and Bioaccumulation Regulations* under the *Canadian Environmental Protection Act* state in sections 4 and 5:

> 4 A substance is bioaccumulative
>
> (a) when its bioaccumulation factor is equal to or greater than 5 000;
>
> (b) if its bioaccumulation factor cannot be determined in accordance with a method referred to in section 5, when its bioconcentration factor is equal to or greater than 5 000; and
>
> (c) if neither its bioaccumulation factor nor its bioconcentration factor can be determined in accordance with a method referred to in section 5, when the logarithm of its octanol-water partition coefficient is equal to or greater than 5.
>
> 5 The determination of persistence and bioaccumulation with respect to a substance under sections 3 and 4 must be made in accordance with generally recognized methods of the Organisation for Economic Co-operation and Development (OECD) or of some other similar organisation or, if no such methods exist, in accordance with generally recognized methods within the scientific community and taking into account the intrinsic properties of the substance, the ecosystem under consideration and the conditions in the environment.

The ECHA found that the criteria for BAF and Log KOW were met, and the finding that the BAF was met is conclusive of the issue in accordance with the waterfall set out in the *Persistence and Bioaccumulation Regulations*. Moreover, there is no basis for the "weight of evidence" approach set out in the *Persistence and Bioaccumulation Regulations*. By virtue of the discrepancy in findings, concerns are raised about the approach of PMRA to the Toxic Substances Management Policy or about the evidence and weight of evidence determinations used by PMRA in making its determination on persistence and bioaccumulation.

3. The advice of an Expert Review Panel would Assist

We have raised a fundamental concern about the conclusion of the evaluation, and various specific objections about most of the Listed Uses. The specific objections point out that PMRA failed to perform an adequate risk assessment with respect to the risks to the environment arising specifically from exposure associated with the Listed Uses, and the objections also provide scientific basis and evidence to raise doubt about the assumptions made, information used and conclusions reached in the approach of the PMRA in its assessment of environmental risk and value of chlorpyrifos.

The advice of expert scientists would assist in assessing the exposure to the environmental arising from uses of chlorpyrifos, and also in pursuing the lines of reasoning and evidence presented herein that raise doubt about the validity of PMRA's assessment of chlorpyrifos. The advice of expert scientists would also assist in guiding the regulator on what registration amendments would be required to address risks of concern.

Respectfully Submitted,

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On the unseeded Territory of the
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J0R 1R1
Per: Michel Gaudet, Executive Director

This is **Exhibit "E"** referred to in the affidavit of **Mary Lou McDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this this 3rd day of November, 2021.

_____

Commissioner for Taking Affidavits
(or as may be)

Minister of Health Patty Hajdu, PC, MP
c/o Pest Management Regulatory Agency
Health Canada
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Ottawa, Ontario AL: 6606D2 K1A 0K9
By Email to: hc.pmra-info-arla.sc@canada.ca
And to: hcminister.ministresc@canada.ca

February 8, 2021

Re: Notice of Objection to the Re-Evaluation Chlorpyrifos and its Associated End-use Products (Environment) RVD2020-14 and PRVD2019-05 Chlorpyrifos "Consultation Document" which was initially and most recently subjected to a full environmental assessment for agricultural uses in 1969

Dear Minister Hajdu,

I am writing on behalf of the non-profit public health organization, the Centre for Health Science and Law (CHSL) to register a formal Notice of Objection to the Pest Management Regulatory Agency's decision concerning the pesticide Chlorpyrifos pursuant to section 35 of the *Pest Control Products Act* (the "Act") which states:

> *35 (1) Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.*

Re-Evaluation Chlorpyrifos and its Associated End-use Products (Environment) RVD2020-14 is dated December 10, 2020.

1. Absence of a review of the health evidence

The December 2020 decision pertains only to environmental (and value) impact, not the health impact of Chlorpyrifos. The proposed re-evaluation decision, released in May 2019, promised that the "[human health assessment] update will be presented in a future publication."

The PMRA, exercising delegated authority from the Minister of Health, is obliged by section 2(2) of the *Pest Control Products Ac*t to assess whether the "health and environmental risks and the value of the pest control product are acceptable," by sections 7(7) and 19(2) to follow a "scientifically based approach," and by section 20(2) to apply the "precautionary principle" in doing so.[1]

[1] Available at: https://laws-lois.justice.gc.ca/PDF/P-9.01.pdf The "precautionary principle" requires making decision that are more protective of health where there is scientific uncertainty about risk. See: Privy Council Office 2003. http://publications.gc.ca/collections/Collection/CP22-70-2003E.pdf

Since 2013, only two of the PMRA's 101 re-evaluations of pest control products omitted a health assessment, both in extenuating circumstances. One pesticide was banned for the use under review solely on the basis of the environmental assessment and the other re-evaluation was undertaken primarily to address pressing concerns about bee pollination.[2] No extenuating circumstances for delaying the health assessment were presented in with the Chlorpyrifos consultation decision in 2019 or the supplementary reasons and final decision in 2020.

Importantly, the decision to delay the Chlorpyrifos health assessment was announced nearly two years ago. A similar promise was made in 2007 to complete an environmental assessment of Chlorpyrifos by the end of 2008, but the next review was published in 2019, 12 years later. Delay favours the commercial ambitions of registrants; delay does not serve public health or the natural environment. Furthermore, publishing a decision that gives a regulatory green-light to a substance after assessing only two prerequisites of the regulatory decision (environment and value, not health) that are mandated by Parliament under the *Pest Control Products Act* may create an industry expectation that continued use of Chlorpyrifos is acceptable.

2. Concerns about transparency

a. Toxicity and quantities of Chlorpyrifos sold were not stated in the 2019 consultation decision or the 2020 final re-evaluation decision, and LD_{50} is not required to be reported on labels.

While the measure of toxicity of pesticides is relevant to human health risks (the subject of the yet-to-be published document), it is also relevant to environmental risk assessments because it informs the analysis about risk to wild animals, domesticated animals, and drinking water supplies. The *Pest Control Products Sales Report for 2018*—which was not truly published, but available on-request to PMRA—describes the amount of Chlorpyrifos sold in Canada that year as between 100,000 and 500,000 KG.[3] This is a highly and needlessly vague description. The lack of precision appears contrary to a Government of Canada undertaking to provide non-financial data at the time the enabling regulations were published.[4]

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[2] See links to summaries of 101 of the 271 Re-Evaluation Decisions completed since the *Pest Control Products Act* received Royal Assent in 2002 at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates.html#rvd-drv Summaries of decision have not been published for Re-evaluation decisions completed prior to 2014.

Although summaries of PMRA decisions prior to 2014 are not available on-line and full text of decisions are only available on-request to the PMRA, the two pesticides for which no health assessment was conducted included: ailed to include a health impact assessment:

- strychnine in 2020, which was banned for the relevant uses on the basis of the environmental assessment alone, and
- Imidacloprid in 2019, which was focussed on addressing pressing concerns and mitigation measures to protect pollinating bees.

[3] The PMRA Report to Parliament for 2018 is not published, but is available on request from *Pest Control Products Sales Report for 2018* since approximately October 8, 2020 from https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/pest-control-products-sales-report.html

[4] Canada Gazette Part II, Vol. 140, No. 23, 2006-11-15 SOR/DORS/2006-261 at p. 1679 and 1685 states, in part:

Reporting of pesticide sales information is a critical piece of an integrated system for obtaining comprehensive information on the extent of pesticide use in Canada and of particular interest to provincial and territorial regulators…PMRA must ensure that the public is allowed access to information in the Register, such as sales information, while at the same time preventing the monetary value of sales from being disclosed.

Available at: http://www.gazette.gc.ca/rp-pr/p2/2006/2006-11-15/pdf/g2-14023.pdf

The reported 100,000-500,000 KG of Chlorpyrifos sold in 2018 may appear small compared to the 40,878,698 KG of Glyphosate (Canada's most widely used pesticide) that PMRA acknowledged was sold in Canada the same year. [5] However, Chlorpyrifos is vastly more toxic than Glyphosate per unit of weight. The acute oral LD_{50} for laboratory mice is estimated to be 60 mg/kg of body weight for Chlorpyrifos[6] and 10,000 mg per KG of bodyweight for Glyphosate,[7] making Chlorpyrifos approximately 167 times more toxic per on a gram-for-gram basis than glyphosate and making the 82-400-fold lower amounts than Glyphosate sold no less concerning.

According to *REV-2007-01 (Chlorpyrifos)*, Health Canada considers this pesticide to be "highly toxic." In that report, Health Canada indicated that it employed a stricter approach to acute toxicity—measured in LD_{50}, the dose at which oral consumption leads to the death of 50% of the subject animals—than the WHO, concluding:

> *While a lethal dose 50% (LD50) of 50–200 mg/kg bw does correspond to "moderately hazardous" under the World Health Organization classification scheme, the PMRA considers an LD50 of less than 500 mg/kg bw to be highly toxic*.[8]

PMRA described the acute oral LD_{50} for Chlorpyrifos in mammals in its *PACR2003-03 Consultation Decision* as in the range of 97-530 mg per KG of bodyweight.[9] This corresponds to an acute lethal dose for a 75-KG farm worker in the range of 7-40 grams, i.e., little over a single fluid ounce and possibly less than a tablespoon. This seems like a vital piece of information that has not yet been conveyed to users on labels. Presumably, serious non-lethal harm can be caused by lower doses, especially during repeated applications or in sensitive people.

Taking the mouse-toxicity metric into account, the amount of Chlorpyrifos sold in Canada in 2018 was equivalent in toxicity to approximately 17-85 million KG of glyphosate. This is the same order of magnitude of the largest selling pesticide in Canada whose recent Re-Evaluation in Canada is presently being judicially reviewed in the Federal Court of Appeal.

CHSL submits that both the precise amount of Chlorpyrifos sold in Canada each year and its LD_{50} are known to PMRA should have been important elements of regulatory decisions and mitigation measures. The amount of Chlorpyrifos and its LD_{50} toxicity metric should have been reported in the re-evaluation decisions because they are centrally relevant to both environmental and health risks.

The LD_{50} and the amount posing such a risk to a typical 75 KG farmer or agricultural worker should also be prominently reported on product labels to help users assess the importance of wearing personal protective equipment (such as masks, gloves, and protective clothing) and taking other mitigation measures (like

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[5] The precise amount of Glyphosate that was sold in 2018 was disclosed to CHSL by PMRA pursuant to an Access to Information Program request filed under the *Access to an Information Act*. See: ATIP 2020-000678 on file with the author and accessible by further ATIP request at: https://atip-aiprp.tbs-sct.gc.ca/en/ATI/Registration/SignOn?p=1a

[6] National Pesticide Information Center. Oregon State University. 2011 Chlorpyrifos Technical Fact Sheet: http://npic.orst.edu/factsheets/archive/chlorptech.html

[7] National Pesticide Information Center. Oregon State University. 2011 Glyphosate Technical Fact Sheet: http://npic.orst.edu/factsheets/archive/glyphotech.html

[8] PMRA. *REV-2007-01 (Chlorpyrifos)*. Available on request from: https://health.canada.ca/en/health-canada/corporate/request-publication-form.html?title=PMRA%20(REV2007-01)%20Update%20on%20the%20Re-evaluation%20of%20Chlorpyrifos

[9] PMRA. Proposed Acceptability for PACR2003-03 Continuing Registration, Phase 2 of the Re-evaluation of Chlorpyrifos. (Ottawa: PMRA, 2003) at 10. This report is available by request to hc.pmra.info-arla.sc@canada.ca .

decontamination). This information has been known for many years by manufacturers and PMRA and their disclosure should not be delayed pending the outcome of a long-delayed health assessment.

b. **Reading room access falls short of transparency.**

While the PMRA offers access to "confidential" documents in the application record, it appears to treat the entire application record as confidential (and/or co-mingles confidential and publicly accessible information). PMRA obliges citizens and environmental or public health advocates to sign notarized, non-disclosure agreements enforced by the threat of criminal sanction in order to see any documents in the application record Reading Room. Because the application record is only available for viewing in an Ottawa reading room and likely consists of tens of thousands of pages of material,[10] the disclosure of which is subject to criminal prosecution, the Objection process does not provide a meaningful opportunity to scrutinize the basis for the PMRA decision. Travel restrictions related to COVID-19 further conceal these records from the Canadian public. The necessity of travel to an Ottawa reading room during the Internet Age unjustifiably obstructs transparency.

Furthermore, the justification for protecting the confidentiality of test data and other documents in the re-evaluation record appears unclear in light of the following PMRA policy as stated on its website:

> ***Inspection of Confidential Test Data Supporting Pesticide Registration Decisions…***
>
> ***2.2 What Is Not Available for Inspection***
>
> *Any personal information or confidential business information (CBI) is removed from the test data before being made available for inspection. The PCPA clearly defines CBI as:*
>
> - *manufacturing or quality control processes;*
> - *methods for determining the composition of the product;*
> - *monetary value of pesticide sales, and other financial or commercial information; and*
> - *the identity and concentration of formulants and contaminants in a pesticide, other than those considered to be of health or environmental concern.*[11] [underscoring added]

If "confidential business information" (CBI) and "personal information" are not available for public viewing, why must Non-Disclosure Agreements be signed to view the remaining non-confidential records?

c. **Reading Room access to printed materials is not meaningful for performing quantitative analysis of test data.**

Because the bulk of the Reading Room documents consist of manual printouts of study data, it is impracticable

[10] Jason Flint, Director General, Policy, Communications and Regulatory Affairs Directorate, Pest Management Regulatory Agency testified "When a new pesticide is registered or a new active ingredient is registered, a typical submission comes to us with about 30,000 pages of scientific studies." Standing Senate Committee on Agriculture and Forestry. Issue No. 67 – Evidence. May 28, 2019 (Available at: https://sencanada.ca/en/Content/Sen/Committee/421/AGFO/67ev-54822-e).

[11] PMRA. Inspection of Confidential Test Data Supporting Pesticide Registration Decisions - Guidance Document. Ottawa. 2018. Available at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry/inspection-confidential-test-data-supporting-pesticide-registration-decisions-guidance-document.html

to the point of impossible for observers to conduct quantitative analysis of such data. For greater clarity, it is impossible to re-type thousands of pages of data into software datafiles in 60 days even if it were permitted to do so by the non-disclosure agreement. There is no indication in the decision of the format in which data are provided by the registrants to PMRA. If, for instance, companies provide data to PMRA in print or PDF format, it would constrain the capacity of the PMRA itself to conducts its own analysis and would raise questions about the willingness of PMRA to accept data in this format.

d. **The "final" decision is actually a set of supplementary reasons, not a stand-alone decision.**

While it seems to follow the customary approach for the PMRA, the document entitled "*Re-Evaluation Decision 2020-14"* is more accurately described as supplementary reasons for the consultation decision called "*PRVD2019-05 Chlorpyrifos Consultation Document."* In this respect, the decision does not seem transparent. Interested parties who request the final decision for the purposes of registering an Objection will be provided with only with partial reasons if they do not file additional requests for disclosure.

e. **The *Re-Evaluation Chlorpyrifos and its Associated End-use Products (Environment) RVD2020-14 was* not truly "published" in either the traditional or modern sense of the word.**

The *Pest Control Products Act* states, that:

> *28 (2) To initiate a consultation under subsection (1), the Minister shall make public a consultation statement and shall invite any person to send written comments on the proposed decision within the period specified in the statement…*
> *35(1) Any person may file with the Minister…a notice of objection to a decision…within 60 days after the decision statement referred to in subsection 28(5) is made public.* [underscoring added]

This decision, like others rendered by the PMRA, has not be made public by the Government of Canada in either the traditional or modern sense of the word. It has not been published in a report that is accessible in libraries or on the Internet. This decision is only available on request to the PMRA and disclosed on a request-by-request basis. The PMRA's approach is more akin to declassifying a secret file, than publishing it.

3. PMRA test data may be systematically biased in favour of the registrants and pesticide users.

The 2018-2019 PMRA *Report to Parliament* seemed to indicate that the Agency does not perform unannounced inspections of user-farms.[12] The practice of always notifying pesticide users in advance of inspections may reduce the possibility of detecting risky pesticide application practices or Maximum Residue Limit exceedances. If so, this exacerbates the problem of PMRA's reliance on seller-sponsored studies failure to consider the vast majority of studies published in peer-reviewed journals, as noted below. PMRA's job is to ensure that pesticides are safe for humans, safe for the natural environment, and effective; it appears to rely almost entirely on data provided by pesticide manufacturers to make these determinations. If it relies on other research, there is no indication in the consultation or final decisions.

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[12] See: PMRA. *Report to Parliament for 2018-2019.* Ottawa: PMRA, 2019 at pages Publicly Available at: https://www.canada.ca/content/dam/hc-sc/documents/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/annual-report-2018-2019/dtp-annual-report-eng.pdf See also: [12] Stakeholder Information Session. December 15, 2020. Available at: https://video.isilive.ca/hcsc/2020-12-15/english/ or by request to hc.pmra.publications-arla.sc@canada.ca

Despite the regulatory requirement to report scientific studies,[13] the fact that registrants reported only eight "scientific studies" on Chlorpyrifos between the 14 years between 2007 and 2021 is indicative of registrants' failure to fund published studies (of which several hundred were published each year) and inclination to report relatively inconsequential studies or studies that are conducive to government approval. Of the eight studies, none was published in a scientific journal and only two were cited by PMRA in either *RVD2020-14 and PRVD2019-05.*[14]

4. The impact of "banning" uses of Chlorpyrifos is obfuscated by the failure of PMRA to disclose the actual amounts of Chlorpyrifos sold annually and diminished by weak regulatory restrictions.

According to a CBC media report, this pesticide was initially approved for sale in Canada in 1969 (52 years ago) and slated to be banned in 2000.[15] That media report stated, in part:

> *Health Minister Allan Rock said his department's Pest Management Regulatory Agency had been trying to get companies to voluntarily withdraw it. But he accused them of reneging on a deal, which forced him to ban the chemical directly. "We are going to impose unilaterally, using our authority as a government, that the product come off the market," Rock told MPs. "When we finish the scientific work to uphold that approach, that is the step we are going to take to protect the health of all Canadians and particularly children."*

Health Canada did not begin collecting information about the amount of pesticides sold in Canada until 2007. That year, the *Pest Control Products Sales Reports* indicates that 500,000-1,000,000 KG of Chlorpyrifos was sold in Canada. By the following year, it described the amount sold as declining to some unspecified amount between 100,000 and 500,000 KG.[16] The reduction may have been as little as 1 KG per year or as much as 900,001 KG. (CHSL's request to obtain the precise amount for each year, filed under the *Access to Information Act* on February 4, 2021, is pending.)

However, according to *PRVD2019-05 Chlorpyrifos "Consultation Document,"* the "Phase 1" decision in 2000[17] only prohibited the residential use of Chrlorpyrifos and agricultural uses on three crops (tomatoes, apples and grapes).

PMRA's 2007 "*Re-Evaluation Note*" contained interim measures and the promise of a full environmental

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[13] *Pest Product Control Act and Pest Control Products Incident Reporting Regulations*, SOR/2006-260. Available at: https://laws-lois.justice.gc.ca/PDF/SOR-2006-260.pdf

[14] See: https://pesticide-registry.canada.ca/en/incident-report-search.html

[15] CBC. Canada to ban use of common insecticide. June 10, 2000. Available at: https://www.cbc.ca/news/canada/canada-to-ban-use-of-common-insecticide-1.227955 The "Phase 1" decision, PMRA (REV2000-05) Chlorpyrifos, can be obtained from PMRA at: https://health.canada.ca/en/health-canada/corporate/request-publication-form.html?title=PMRA%20(REV2000-05)%20Chlorpyrifos

[16] The *Pest Control Products Sales Reports* for 2007 and 2018 are not published, but the 2007 report is available by request to hc.pmra.info-arla.sc@canada.ca and the 2018 is available by request filed online at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/pest-control-products-sales-report.html

[17] The "Phase 1" decision, *REV2000-05 Chlorpyrifos*, can be obtained from PMRA at: https://health.canada.ca/en/health-canada/corporate/request-publication-form.html?title=PMRA%20(REV2000-05)%20Chlorpyrifos

assessment by 2008, however, no further environmental assessment was published until 2019, 12 years later[18] and permitted many agricultural uses.

Likewise, *RVD2020-14* gave an additional two-year grace period for complying with the prohibition on uses for canola without quantifying the scope of that exception. Canola is planted on 21 million acres in Canada (nearly one-fifth of all cropland) and generates 20 million tonnes of canola annually.[19] If dangerous pesticides are:

- labelled without precise risk warnings (including estimates),
- permitted for major crop uses,
- in an inspection regime where site visits are always announced in advance,[20]
- in a compliance regime where 99% of regulatory responses to violations are warning letters,[21] and
- on the rare occasions when fines were levied for pesticide-related violations, they usually range from $2,000 to $4,000 and rarely exceed $12,000, all of which are small compared to crop sales volumes[22]

users may be motivated to take excessive risks in using Chlorpyrifos.

5. Studies published in peer-reviewed scientific journals were almost entirely ignored by PMRA and seller-sponsored studies were considered with no discernable safeguards for the conflicts-of-interest inherent in such studies.

The *Pest Control Products Act* states:

> *4 (1) In the administration of this Act, the Minister's primary objective is to prevent unacceptable risks to individuals and the environment from the use of pest control products…*
>
> *19 (1) During an evaluation that is done in the course of a re-evaluation or special review,…*
>
> *(b) the registrant has the burden of persuading the Minister that the health and environmental risks and the value of the pest control product are acceptable; …*
>
> *20 (2) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall (a) apply a scientifically based approach;*

[18] PMRA (REV2007-01) Update on the Re-evaluation of Chlorpyrifos. Available by request to PMRA at: https://health.canada.ca/en/health-canada/corporate/request-publication-form.html?title=PMRA%20(REV2007-01)%20Update%20on%20the%20Re-evaluation%20of%20Chlorpyrifos

[19] See: https://www.canolacouncil.org/markets-stats/

[20] Stakeholder Information Session. Available at: https://video.isilive.ca/hcsc/2020-12-15/english/ or by request to hc.pmra.publications-arla.sc@canada.ca

[21] The PMRA *Report to Parliament* indicates that 99% of enforcement actions (983 of 990 in 2018-2019) were warning letters, suggesting that failures to follow label-instruction may be widespread, especially recognizing that not all farms were inspected all the times. See: https://www.canada.ca/content/dam/hc-sc/documents/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/annual-report-2018-2019/dtp-annual-report-eng.pdf

[22] Document: PMRA enforcement bulletin for 2016-2021: https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/compliance-enforcement/enforcement-bulletins.html

Neither *RVD2020-14* nor *PRVD2019-05* indicate any proactive efforts by PMRA to review scientific research considering Chlorpyrifos published in peer reviewed scientific journals let alone efforts to undertake a systematic review of this literature.

This relevant published scientific literature is vast and the PMRA should not depend on haphazardly resourced external parties—such as environmental or public health NGOs—to bring studies to its attention. For example, according to the public-access index of scientific research published in peer-review journals, https://www.sciencedirect.com/search?tak=chlorpyrifos&show=100, 2,708 studies included the highly specific search term Chlorpyrifos in the title, abstract or author-specified key words as of February 8, 2021. These studies were mostly published in environmental or agricultural science journals. Of those, 2,223 articles were published by the end of 2018, in time to be considered prior to the publication of the 2019 Chlorpyrifos consultation proposal.[23] (Many more articles considered Chlorpyrifos in study analysis, for instance, in comparison to other pesticides.)

By stark contrast, of the total of 180 studies cited in either the PMRA's consultation or final decisions on its environment (and value) assessment, only eight were published in peer-reviewed journals.

According to this analysis, the PMRA ignored more than 99.6% of relevant studies published in peer-reviewed scientific journals by 2018 and, instead, relied mainly on 172 seller-sponsored studies. This approach seems to be contrary to the Minister's statutory duty. This is tantamount to a rejection of most science, and most independent and even government-funded independent science. The *Pest Control Products Act* expressly requires the Minister of Health to re-evaluate pesticides following a "scientifically based approach" and the "precautionary principle."[24]

6. Conclusion

For all of these reasons, we urge the Pest Management Regulatory Agency to reconsider *Re-Evaluation Chlorpyrifos and its Associated End-use Products (Environment) RVD2020-14* and consider these comments in its promised health assessment of Chlorpyrifos. CHSL submits that lack of transparency, and bias in favour of industry research and against published in peer-review systemically raises scientifically founded doubt about the reasonableness of this decision. The complete absence of a health assessment two years later is unjustified, but if PMRA aims to conduct that assessment chiefly on the basis of seller-sponsored studies, its release for consultation will provide little assurance to PMRA is dutifully protecting public health and the environment.

Respectfully submitted,

Bill Jeffery, BA, LLB
Executive Director and General Counsel
Centre for Health Science and Law (CHSL)

[23] See: https://www.sciencedirect.com/search?tak=chlorpyrifos
[24] Section sections 7, 19, and 20 of *Pest Control Products Act*, S.C. 2002, c. 28

This is **Exhibit "F"** referred to in the affidavit of **Mary Lou McDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 3rd day of November, 2021.

Commissioner for Taking Affidavits
(or as may be)

Re-evaluation Note REV2021-02

Update on the Re-evaluation of Chlorpyrifos

(publié aussi en français)

13 May 2021

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Under the re-evaluation program, Health Canada's Pest Management Regulatory Agency (PMRA) has reviewed chlorpyrifos and its associated uses and implemented several risk reduction measures over the years. In 2000, Health Canada removed all residential uses from chlorpyrifos labels. In addition, Health Canada implemented mitigation measures in 2007 (REV2007-01, *Update on the Re-evaluation of Chlorpyrifos*) to further protect human health and the environment, following an assessment on agricultural and forestry uses. In 2007 (REV2007-01), it was also indicated that an update to the environmental risk assessment for chlorpyrifos would be required.

In December 2020, Health Canada published a re-evaluation decision (RVD2020-14, *Chlorpyrifos and Its Associated End-use Products (Environment)*) based on an updated environmental risk assessment (PRVD2019-05, *Chlorpyrifos and Its Associated End-use Products: Updated Environmental Risk Assessment*). In this decision, Health Canada cancelled almost all agricultural uses due to environmental risks of concern while a few uses were acceptable from the environmental perspective. Cancelled uses/products were to be phased out by 10 December 2023, while two cancelled uses (canola for alfalfa looper and garlic for darksided and redbacked cutworm) were granted an extended phase-out period to December 2024 due to the lack of suitable alternatives with the implementation of additional risk mitigation measures.

Health Canada also informed the public in December 2020 (RVD2020-14) that the human health aspect of chlorpyrifos would be updated based on the additional information generated internationally since our last assessment, and that this update would be presented in a future publication. In order to proceed with the update to the human health risk assessment, Health Canada issued a data call-in notice under paragraph 19(1)(a) of the *Pest Control Products Act*. Registrants of chlorpyrifos failed to satisfy the data requirements. Consequently, Health Canada has cancelled all chlorpyrifos uses/products, including those that remained registered following the environmental risk assessment, in accordance with paragraph 20(1)(a) of the *Pest Control Products Act*. The existing stocks of all chlorpyrifos products in Canada are being phased out with the following timelines:

Last date of sale by registrant:	10 December 2021
Last date of sale by retailers:	10 December 2022
Last date of use for all chlorpyrifos uses/products including canola (for alfalfa looper) and garlic (for darksided and redbacked cutworm)	10 December 2023

The intended work to update the human health assessment is no longer needed as all pest control products containing chlorpyrifos are being cancelled due to failure to satisfy requested data requirements. On this basis, the re-evaluation for chlorpyrifos is now considered complete.

This is **Exhibit "G"** referred to in the affidavit of **Mary Lou McDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 3rd day of November, 2021.

Commissioner for Taking Affidavits
(or as may be)

Health Canada | Santé Canada

Pest Management Regulatory Agency | Agence de réglementation de la lutte antiparasitaire

e-mail: SafeFoodMatters@gmail.com
Reference No. 2021-0623

Mary Lou McDonald, President
Safe Food Matters Inc.
Gilmour, ON
K0L 1W0

Dear Mary Lou McDonald:

Re: Notice of Objection to Re-evaluation Decision RVD2020-14 *Chlorpyrifos and its Associated End-use Products (Environment)*

Your notice of objection regarding the re-evaluation decision for chlorpyrifos; specifically the continued uses for mosquito control, elm bark beetle, mountain pine beetle, and for non-residential structural use and the extended phase out period for use on canola and garlic, filed under subsection 35(1) of the Pest Control Products Act (PCPA), has been screened.

On May 13, 2021, Health Canada published REV2021-02, *Update on the Re-evaluation of Chlorpyrifos* to inform stakeholders that all remaining uses/products of chlorpyrifos are being cancelled and the phase out period is no longer extended for canola and garlic. As a result the PMRA is proposing that the Notice of Objection be closed. Please confirm your agreement to this proposal.

Should you have any questions regarding this letter, please submit them to the Notice of Objection e-mail account (hc.pmra.NoO-AdO.arla.sc@canada.ca) and we will respond as soon as possible. Please quote Reference Number 2021-0623 in any correspondence regarding the Notice of Objection to the re-evaluation of chlorpyrifos.

Sincerely,

Recoverable Signature

X M. E. Silva.

Signed by: Silva, Minoli

Minoli Silva
Director, Registration Directorate
Pest Management Regulatory Agency