To: Minister of Health Patty Hajdu, PC, MP February 8, 2021
c/o Pest Management Regulatory Agency
Health Canada
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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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