



February 8, 2021

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

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

Dear Minister Hajdu,

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

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

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

1. Absence of a review of the health evidence

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

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

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

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

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

2. Concerns about transparency

a. Toxicity and quantities of Chlorpyrifos sold were not stated in the 2019 consultation decision or the 2020 final re-evaluation decision, and LD₅₀ is not required to be reported on labels.

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

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

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

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

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

⁴ Canada Gazette Part II, Vol. 140, No. 23, 2006-11-15 SOR/DORS/2006-261 at p. 1679 and 1685 states, in part: *Reporting of pesticide sales information is a critical piece of an integrated system for obtaining comprehensive information on the extent of pesticide use in Canada and of particular interest to provincial and territorial regulators...PMRA must ensure that the public is allowed access to information in the Register, such as sales information, while at the same time preventing the monetary value of sales from being disclosed.*

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

The reported 100,000-500,000 KG of Chlorpyrifos sold in 2018 may appear small compared to the 40,878,698 KG of Glyphosate (Canada's most widely used pesticide) that PMRA acknowledged was sold in Canada the same year.⁵ However, Chlorpyrifos is vastly more toxic than Glyphosate per unit of weight. The acute oral LD₅₀ for laboratory mice is estimated to be 60 mg/kg of body weight for Chlorpyrifos⁶ and 10,000 mg per KG of bodyweight for Glyphosate,⁷ making Chlorpyrifos approximately 167 times more toxic per on a gram-for-gram basis than glyphosate and making the 82-400-fold lower amounts than Glyphosate sold no less concerning.

According to *REV-2007-01 (Chlorpyrifos)*, Health Canada considers this pesticide to be “highly toxic.” In that report, Health Canada indicated that it employed a stricter approach to acute toxicity—measured in LD₅₀, the dose at which oral consumption leads to the death of 50% of the subject animals—than the WHO, concluding:

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

PMRA described the acute oral LD₅₀ for Chlorpyrifos in mammals in its *PACR2003-03 Consultation Decision* as in the range of 97-530 mg per KG of bodyweight.⁹ This corresponds to an acute lethal dose for a 75-KG farm worker in the range of 7-40 grams, i.e., little over a single fluid ounce and possibly less than a tablespoon. This seems like a vital piece of information that has not yet been conveyed to users on labels. Presumably, serious non-lethal harm can be caused by lower doses, especially during repeated applications or in sensitive people.

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

CHSL submits that both the precise amount of Chlorpyrifos sold in Canada each year and its LD₅₀ are known to PMRA should have been important elements of regulatory decisions and mitigation measures. The amount of Chlorpyrifos and its LD₅₀ toxicity metric should have been reported in the re-evaluation decisions because they are centrally relevant to both environmental and health risks.

The LD₅₀ and the amount posing such a risk to a typical 75 KG farmer or agricultural worker should also be prominently reported on product labels to help users assess the importance of wearing personal protective equipment (such as masks, gloves, and protective clothing) and taking other mitigation measures (like

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

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

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

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

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

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

b. Reading room access falls short of transparency.

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

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

Inspection of Confidential Test Data Supporting Pesticide Registration Decisions...

2.2 What Is Not Available for Inspection

Any personal information or confidential business information (CBI) is removed from the test data before being made available for inspection. The PCPA clearly defines CBI as:

- *manufacturing or quality control processes;*
- *methods for determining the composition of the product;*
- *monetary value of pesticide sales, and other financial or commercial information; and*
- *the identity and concentration of formulants and contaminants in a pesticide, other than those considered to be of health or environmental concern.*¹¹ [underscoring added]

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

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

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

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

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

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

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

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

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

The *Pest Control Products Act* states, that:

28 (2) To initiate a consultation under subsection (1), the Minister shall make public a consultation statement and shall invite any person to send written comments on the proposed decision within the period specified in the statement...

35(1) Any person may file with the Minister...a notice of objection to a decision...within 60 days after the decision statement referred to in subsection 28(5) is made public. [underscoring added]

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

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

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

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

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

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

According to a CBC media report, this pesticide was initially approved for sale in Canada in 1969 (52 years ago) and slated to be banned in 2000.¹⁵ That media report stated, in part:

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

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

However, according to *PRVD2019-05 Chlorpyrifos “Consultation Document,”* the “Phase 1” decision in 2000¹⁷ only prohibited the residential use of Chlorpyrifos and agricultural uses on three crops (tomatoes, apples and grapes).

PMRA’s 2007 “*Re-Evaluation Note*” contained interim measures and the promise of a full environmental

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

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

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

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

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

assessment by 2008, however, no further environmental assessment was published until 2019, 12 years later¹⁸ and permitted many agricultural uses.

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

- labelled without precise risk warnings (including estimates),
- permitted for major crop uses,
- in an inspection regime where site visits are always announced in advance,²⁰
- in a compliance regime where 99% of regulatory responses to violations are warning letters,²¹ and
- on the rare occasions when fines were levied for pesticide-related violations, they usually range from \$2,000 to \$4,000 and rarely exceed \$12,000, all of which are small compared to crop sales volumes²²

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

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

The *Pest Control Products Act* states:

4 (1) In the administration of this Act, the Minister's primary objective is to prevent unacceptable risks to individuals and the environment from the use of pest control products...

19 (1) During an evaluation that is done in the course of a re-evaluation or special review,...

(b) the registrant has the burden of persuading the Minister that the health and environmental risks and the value of the pest control product are acceptable; ...

20 (2) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall (a) apply a scientifically based approach;

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

¹⁹ See: <https://www.canolacouncil.org/markets-stats/>

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

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

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

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

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

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

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

6. Conclusion

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

Respectfully submitted,



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²³ See: <https://www.sciencedirect.com/search?tak=chlorpyrifos>

²⁴ Section sections 7, 19, and 20 of *Pest Control Products Act*, S.C. 2002, c. 28