Dr. Marcos A. Orellana
Special Rapporteur on Toxics and Human Rights
Office of the High Commissioner for Human Rights
United Nations Office Geneva, Avenue Giuseppe Motta 48
CH-1202 Geneva, Switzerland
By email to: srtoxicshr@ohchr.org

March 15, 2021

Re: Call for submission concerning upcoming report on the right to benefit from scientific progress

Dear Special Rapporteur Dr. Marcos A. Orellana:

I am writing on behalf of the non-profit public health organization, the Centre for Health Science and Law (CHSL) to inform your upcoming thematic report. CHSL encourages your efforts to emphasize the importance of governments making decisions based on the best available evidence, applying the precautionary principle when the circumstances require doing so (not just when favoured by politically expedience), and, above all, protecting public health and the environment. Ensuring that public interest is the guiding principle of public policy requires reconciling human rights with business interests, especially because the global revenue of many pesticide manufacturers vastly exceed the GDPs of so many low- and middle-income countries. Consider recognizing the progress made by the United Nations Human Rights Council's efforts to negotiate a legally binding treaty by its "Open-ended intergovernmental working group on transnational corporations and other business enterprises with respect to human rights."

Please consider our recent comment to the United States Environmental Protection Agency on its proposal to re-register the pesticide Chlorpyrifos (appended), our recent Notice of Objection to a re-evaluation decision on Chlorpyrifos by the Canadian Pest Management Regulatory Agency (PMRA, also appended), and our motion to intervene in a judicial review of a 2019 decision by the Canadian Federal Court of Appeal of the PMRA's re-evaluation decision on glyphosate, especially the judge's decision under appeal (at pp. 275-301), a summary of new evidence proposed to be admitted on appeal (summarizing at pp. 460-477 the documentary evidence at pp. 322-424), and CHSL's draft memorandum of fact and law (at pp., 478-528) all of which is available online.[1]

We also urge you to consider today's comments before finalizing your September 2020 advanced, unedited (based on your 2019 Canadian country visit), especially considering that ss. 80.1(1) and 90 of the *Pest Control Products Act* mandated its second, as yet unfulfilled seven-year review by June 28, 2020.

Respectfully submitted,

Bill Jeffery, BA, LLB
Executive Director and General Counsel
Centre for Health Science and Law (CHSL)
PO Box 4880, Station E, Ottawa, Ontario K1S 5J1 CANADA

[1] CHSL's motion for leave to intervene was opposed by the PMRA and denied without prejudice to our right to appeal.

TO: Ms. Jane Nishida, Acting Administrator
AND TO: Mr. Michael S. Regan, Nominee Administrator
Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001 USA
By upload to: https://www.federalregister.gov/documents/2020/12/07/2020-26386/pesticide-registration-review-proposed-interim-decision-for-chlorpyrifos-notice-of-availability#open-comment

March 5, 2021

Re: ***Pesticide Registration Review; Proposed Interim Decision for Chlorpyrifos***[1]

Dear Acting Administrator Ms. Nishida and Nominee Administrator Mr. Regan,

I am writing on behalf of the non-profit public health organization, the Canadian Centre for Health Science and Law (CHSL) to urge the U.S. Environmental Protection Agency to consider the entirety of scientific evidence concerning the adverse human health risks of Chlorpyrifos and discontinue all uses of Chlorpyrifos.

Key findings about the human health safety profile of this pesticide were encapsulated by 71 independent health-science experts in comments submitted to the EPA by the Emmett Harvard Law School Environmental Law & Policy Clinic,[2] and the Boston College Program for Global Public Health and the Common Good, and the Global Observatory on Pollution and Health,[3] including Canadian professor Bruce P. Lanphear, MD, MPH, an Investigator at the British Columbia Children's Hospital Research Institute and Professor of Health Sciences at Simon Fraser University in Vancouver.

In particular, both groups advised that the EPA's metric for detecting harmful levels of exposure to irreversible neurological harm is unfit for the task. For instance, the Boston-College-led group of 56 nation-wide experts characterized the EPA laboratory technique to detect Chlorpyrifos's influence on the inhibition of the enzyme acetylchlolinesterase (AChE-inhibition) as "uninformative," "insensitive," and "unscientific." By contrast, the same 56 experts concluded that infants and young children are:

> *exquisitely sensitive to harm from exposure to organophosphates like chlorpyrifos [and are]…commonly exposed to this insecticide…Chlorpyrifos' capacity to disrupt neurological development should be the basis for determining whether existing chlorpyrifos tolerances comply with the "reasonable certainty of no harm" standard in the FQPA. We conclude they do not.*

The statutory standard of safety was articulated slightly differently by our two legislatures:

- *"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"* in Canada;[4] and
- *"no unreasonable adverse effects*" in the United States according to the EPA proposal.[5]

However, the result has been the same in both interim Chlorpyrifos decisions: restriction of only some uses based on review processes that failed to consider—or imprudently dismissed—important scientific evidence.

On March 4, 2021, Seattle-based Earth Justice issued a 91-page report to the EPA concluding:

> *More than five years ago, the Ninth Circuit [Court] called EPA's delay in protecting people from chlorpyrifos "egregious" and imposed deadlines "necessary to end this cycle of incomplete responses, missed deadlines, and unreasonable delay." In re PANNA v. EPA, 798 F.3d 809, 811, 813 (9th Cir. 2015). Unfortunately, the Trump administration evaded the law and defied the science to avoid taking action to protect workers from acute poisonings and children from learning disabilities and IQ deficits. With the change in administrations, EPA is now revisiting the Wheeler order, which refused to grant the 2007 petition to ban food uses of chlorpyrifos…The science is unequivocal. Chlorpyrifos causes harm to the developing brain, leaving children with learning disabilities, reduced IQ, and other neurodevelopmental impairments. It is long past time to protect our children from chlorpyrifos. Because EPA cannot find reasonable certainty of no harm from chlorpyrifos, it must finalize its proposed rule revoking all chlorpyrifos tolerances and make that rule effective within 180 days, as proposed. EPA should thereafter cancel all uses of chlorpyrifos because the food uses are unsafe and other uses cause unreasonable adverse effects to workers and others exposed to the pesticide.*[6]

In 2019, European Food Safety Authority concluded that Chlorpyrifos is not sufficiently safe for use:

> *"Due to the fact that the genotoxic potential of chlorpyrifos remains unclear, toxicological reference values could not be established. Moreover, significant uncertainties were linked to the neurodevelopmental toxicity study, where effects were observed at the lowest dose tested in rats (decrease in cerebellum height corrected by brain weight). These concerns were supported by the available epidemiological evidence related to developmental neurological outcomes in children. In the absence of toxicological reference values, a risk assessment for consumers, operators, workers, bystanders and residents cannot be conducted. This issue represents a critical area of concern for chlorpyrifos. In addition, the recorded toxicological effects meet the criteria for classification as toxic for reproduction category 1B (regarding developmental toxicity). Based on the above results, it is considered that the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009 are not met."*[7]

Although Health Canada's Pest Management Regulatory Agency's recent decision did end uses for many applications of Chlorpyrifos, CHSL's Notice of Objection (appended) to ***Re-Evaluation Chlorpyrifos and its Associated End-use Products (Environment) RVD2020-14*** submitted that the PMRA:

- failed to conduct a health assessment as required by the *Pest Control Products Act*;
- failed to consider the vast majority of scientific research published in peer-review journals (ignoring more that 99% of published studies) contrary to a duty to apply a "scientifically based approach" and the "precautionary principle" mandated by the *Pest Control Products Act*;[8]
- fundamentally failed to make its decision based on a transparent record;
- failed to demonstrably apply conflict of interest safeguards to account for self-serving bias of seller-sponsored studies, which safeguards, though not expressly required by the *Act,* are recognized as important by subordinate regulations governing the appointment of scientific Review Panels;[9]
- failed to concede that extending a permitted use of Chlorpyrifos on canola for four years exempts an oilseed planted on more than 20% of Canadian cropland; and
- failed to require manufacturers to prominently state on labels the estimated LD50 for Chlorpyrifos to alert agricultural workers, farmers and their families of the severe heath risks posed by small amounts.

As Canada's largest trading partner, the Untied States can, presumably, rest assured that Chlorpyrifos residues will decline on most products (except canola oil) in the coming two years. American farmers appear to use more glyphosate (5 million pounds/year, approximately 2.5 million KG) on more products than Canadian farmers (100,000-500,000 KG), though possibly not more on a per-capita or per-yield basis for some products. So much food crosses our borders in both directions that actions of both governments can expose all of us (and consumers of other trading partners with weak regulatory regimes) to risk. Accordingly, consider ensuring that shipments of Chlorpyrifos containers destined to Canada be labelled with warnings that quantify the acute and chronic heath risks to agricultural works, farm neighbours, and consumers, including but not limited to the best estimate of LD50 for humans in milligrams per kilogram of body weight, and relatable amounts for a typical child and adult farm worker (e.g., grams and fractions of a teaspoon). (Further information should alert users to possibility that much lower-dose exposure can cause irreversible neurological impairment.) In principle, doing so is recommended by the World Health Organization/Food and Agriculture Organization *International Code of Conduct on Pesticide Management*. The *Code* encourages *all* member states, especially considering so many have weak pesticide management regimes, to:

> *"promote practices which reduce risks throughout the lifecycle of pesticides, with the aim of minimizing adverse effects on humans, animals and the environment and preventing accidental poisoning resulting from handling, storage, transport, use or disposal, as well as from the presence of pesticide residues in food and feed."*[10]

The World Health Organization / Food and Agriculture Organization *Code* generally promotes behaviour that one might expect from a good neighbour.

Respectfully submitted,

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Ottawa, Ontario K1S 5J1 CANADA
BillJeffery@HealthScienceAndLaw.ca

REFERNECES

[1] EPA's proposed interim registration decision for Chlorpyrifos 60-day consultation from December 7, 2020 to February 5, 2021 was extended by 30 days to March 7, 2021. EPA. Comment Period Extended for Chlorpyrifos Draft Risk Assessments and Proposed Interim Decision for Release: February 5, 2021. Available at: https://www.epa.gov/pesticides/comment-period-extended-chlorpyrifos-draft-risk-assessments-and-proposed-interim-decision

[2] Emmett Harvard Law School Environmental Law & Policy Clinic comments. February 5, 2021. Available at: https://downloads.regulations.gov/EPA-HQ-OPP-2008-0850-1036/attachment_1.pdf

[3] Boston College Program for Global Public Health and the Common Good, and the Global Observatory on Pollution and Health comments on February 4, 2021. Available at: https://downloads.regulations.gov/EPA-HQ-OPP-2008-0850-1008/attachment_1.pdf

[4] The Act Section 2(2) states:

Acceptable risks

(2) For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is 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.

And section 4 states:

Primary objective Objectif premier 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.

[5] Environmental Protection Agency. Chlorpyrifos Proposed Interim Registration Review Decision, Case Number 0100, December 2020 Docket Number EPA-HQ-OPP-2008-0850 www.regulations.gov at page 4. Available at: https://www.epa.gov/sites/production/files/2020-12/documents/chlorpyrifos_pid_signed_120320.pdf

[6] Earth Justice, et al. Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment. March 4, 2021. Available at: https://earthjustice.org/sites/default/files/files/2021.03.04_comments_submitted_by_earthjustice_0.pdf

[7] EFSA. *Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance Chlorpyrifos, July 2019*. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/5809 Affirmed in a November 2019 update available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5908

[8] *Pest Control Products Act*, S.C. 2002, c. 28., ss. 7, 19, 20. Available at: https://laws-lois.justice.gc.ca/PDF/P-9.01.pdf

[9] *Pest Control Product Act Review Panel Regulations*, SOR/2008-22, s 4 (c, d). Available at: https://laws-lois.justice.gc.ca/PDF/SOR-2008-22.pdf

[10] FAO/WHO. *The International Code of Conduct on Pesticide Management.* Rome. 2014. Available at: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/CODE_2014Sep_ENG.pdf

Health Canada Santé Canada

Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la Loi sur les produits antiparasitaires

Date received – Date reçue	
Submission No. - N° de la demande	

1. Objector Information – Information sur l'opposant

Name – Nom / Corporation – société / Organization – organisation*

Bill Jeffery on behalf of the non-profit public interest organization, the Centre for Health Science and Law (CHSL)

Postal Delivery Address – Adresse de livraison postale* PO Box 4880 Station E

City / Town – Ville*	Prov / State – Province / État*	Country – Pays*	Postal Code / ZIP – Code postal / ZIP*
Ottawa	ON	Canada	K1S 5J1

Phone – Téléphone*	Fax – Télécopieur	E-mail – Courriel
613-565-2140		litigation@healthscienceandlaw.ca

2. Product Information – Information sur le produit*

Name of active ingredient to which the decision relates – Nom de la matière active à laquelle la décision se rapporte*

Chlorpyrifos

Name of end-use product to which the decision relates – Nom de la préparation commerciale à laquelle la décision se rapporte*

All end-use products containing Chlorpyrifos as active ingredient

3. Registration decision to which the objection relates – Décision d'homologation pour laquelle vous déposez un avis d'opposition*

Decision on application – Décision concernant la demande

	Granting registration – Homologation accordée
	Denying registration – Homologation rejetée
	Granting an amendment of a registration – Modification à l'homologation accordée
	Denying an amendment of a registration – Modification à l'homologation rejetée

Decisions on re-evaluation or special review – Décision concernant la réévaluation ou l'examen spécial

X	Confirming registration – Homologation confirmée
	Cancelling registration – Homologation annulée
	Amending registration – Modification à une homologation

4. Date the decision statement was made public – Date de la publication de l'énoncé de décision*

December 10, 2020

5. Area of scientific evaluation to which the objection relates – Volet de l'évaluation scientifique touché par l'avis d'opposition*

X	Health risk assessment (toxicology, food residue, occupational exposure) – Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)
X	Environmental risk assessment (environmental fate, environmental toxicology) – Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie)
	Value and efficacy assessments (crop tolerance, value) – Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection – Fondement scientifique de l'opposition*

Attachment included? – Pièce jointe inclse?	X/ Yes – Oui	No – Non

See the Notice of Objection. Glyphosate applied for desiccation purposes is placing residues in the seeds to that extent that they exceed MRLs and are of concern to human health, especially considering increased consumption of the relevant foods, and that evidence of such translocation and accumulation has not been considered in the Re-evaluation or contemplated in the law.

7. Signature of objector or representative – Signature de l'opposant ou de son représentant	Printed Name – Nom en lettres moulées*	Date*
Bill Jeffery	Bill Jeffery	February 8, 2021

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

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

February 8, 2021

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

Dear Minister Hajdu,

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

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

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

1. Absence of a review of the health evidence

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

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

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

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

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

2. Concerns about transparency

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The *Pest Control Products Act* states, that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The *Pest Control Products Act* states:

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

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

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

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

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

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

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

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

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

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

6. Conclusion

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

Respectfully submitted,

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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