Court File No. T-956-21

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.
and PREVENT CANCER NOW

Applicants

and

ATTORNEY GENERAL OF CANADA and
MINISTER OF HEALTH

Respondents

SECOND AMENDED NOTICE OF APPLICATION

Pursuant to section 18.1 of the *Federal Courts Act*

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED by the applicants. The relief claimed by the applicants appears on the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the applicants. The applicants request that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the applicants' solicitors WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date: ~~June 14, 2021~~
~~October 20, 2021~~
February 10, 2021

Issued by: _____
(Registry Officer)

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APPLICATION

1. This case is about Canada's pest management regulator, the Pest Management Regulatory Agency ("**PMRA**"), delaying, without legal justification, measures to protect the health of Canadians, including protecting children from the risks of brain damage, due to exposure to a dangerous pesticide.

2. This is an application for judicial review of the decision of the Minister of Health ("**Minister**") through the PMRA, to ~~cancel the registration of Chlorpyrifos-containing pest control products for all uses in Canada and~~ to allow the sale and use of ~~the product~~ Chlorpyrifos to continue for a three-year phase-out period after all registrations and uses of the product were cancelled.

3. In a registration decision published on May 13, 2021 the Minister purported to cancel all uses of Chlorpyrifos and its registered end use products. However, the Minister permitted existing stocks of the products to be sold for two more years and permitted the existing stocks to be used for three more years, until December of 2023.

4. The Minister did not update the public registry as required under subsection 42(2)(h) of the *Pest Control Products Act* (the "**Act**" or "***PCPA***") to indicate that all the registrations of pest control products containing Chlorpyrifos were immediately cancelled. Rather, as of June 2021, 24 products continue to be listed as registered and expiry dates for the registrations are stated as ending in December of 2023.

5. The decision to allow the sale and use of Chlorpyrifos over a three-year period was unreasonable, unlawful and made without jurisdiction. The decision was lacking in justification, transparency or intelligibility and was made without regard to the purposes of the *PCPA* or the relevant legal constraints applying to cancellations of registrations in the *PCPA*.

THE APPLICANTS MAKE APPLICATION FOR:

6. The Applicants make application for:

(a) A declaration that the Minister has acted unlawfully and without jurisdiction in applying a three-year phase-out period to the sale and use of Chlorpyrifos;

~~(b) An order setting aside the Minister's decision to allow the continued sale and use of Chlorpyrifos for up to three years;~~

~~(c) In the alternative, an order setting aside the three-year phase-out and remitting the matter back to the Minister to determine if the Minister will impose recall, seizure or disposal procedures that the Minister considers necessary for carrying out the purposes of the Act in accordance with the Court's reasons;~~

(d) An order requiring the Minister to update the public registry indicating that the registrations of all Chlorpyrifos pesticides are cancelled;

~~(e) An order prohibiting the Minister from renewing, reviving or otherwise extending any registrations that have expired or would expire prior to December 2023;~~

(f) An order that each party shall bear their own costs;

(g) In the alternative, an order for costs in favour of the applicants throughout; and

(h) Such further and other relief as counsel may advise and this Honourable Court may deem just.

THE GROUNDS OF THE APPLICATION ARE:

The Parties

7. The applicants, Safe Food Matters Inc. and Prevent Cancer Now (collectively, the "**Applicants**") are non-governmental organizations working to protect the health of the environment and humans by contributing to the development of government policies that limit the use of pest control products and food production technologies

that are harmful. The Applicants have advocated publicly for restrictions on the use of organophosphate pesticides such as Chlorpyrifos.

8. Safe Food Matters Inc. ("**SFM**") has worked to contribute to and advocate for government policies which limit the use of harmful pest control products. SFM has previously participated in consultations conducted by the PMRA on proposed policies and commented on the registration of potentially harmful insecticides.

9. Prevent Cancer Now ("**PCN**") is a not-for profit organization whose mission is to eliminate the preventable contributors to cancer through research, awareness, education and advocacy. As part of this work, PCN publicly advocates for restrictions on the production and use of organophosphate pesticides. PCN participated in the public consultation conducted by the PMRA on the Chlorpyrifos re-evaluation decision.

10. Working with other non-governmental organizations, the Applicants both filed a notice of objection under s. 35(1) of the Act to the PMRA's Chlorpyrifos environmental risk re-evaluation decision, requesting that the PMRA appoint a panel to review its conclusions in the environmental risk assessment.

11. The Applicants have public interest standing. They each have genuine interests in protecting Canadians and Canada's environment from the risk of harm due to pesticides. They have no personal, proprietary or pecuniary interests in the outcome of this application.

12. The Applicants have genuine interests in the lawful administration of the Act, and in the PMRA's compliance with the Act's standards for environmental and health protection. SFM has previously engaged in public interest litigation concerning the Act.

13. The Minister of Health is responsible for administering the Act. The Minister has delegated this responsibility to the PMRA.

The Regulation of Pest Control Products in Canada

14. Subsection 4(1) of the Act enshrines the PMRA's primary mandate as the prevention of "unacceptable risks" to people and the environment from the use of pesticides. Acceptable risk is defined in s. 2(2) of the Act, which provides that "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."

15. The Act sets out a framework for pest control product regulation that requires that strict scientific criteria be met to establish acceptable risk, and places the onus on registrants to meet a high threshold for risk. Under s. 6(1), no person shall manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered, with certain limited exceptions. Under s. 8(4), the Minister must deny an application for registration or amendment to a registration if the Minister does not consider the health or environmental risks of a pest control product to be acceptable. Subsection 7(7)(a) provides that in evaluating health and environmental risks and in determining acceptable risk, the Minister shall apply a scientifically based approach. Subsection 7(6) provides that the applicant has the burden of persuading the Minister that the health and environmental risks and the value of the product are acceptable.

16. Under section 13 of the *Pest Control Products Regulations* SOR2006/-124 ("***Regulations***") the maximum validity period of a registration is the fifth year after the year in which the product is registered.

17. Under section 16 of the *Regulations* the registration of a pest control product may be renewed, on application by the registrant to the Minister, for additional periods of not more than five years each. Sections 6 and 8 of the *Regulations* require information on risks of the pesticide to be included each time the product registration is renewed.

18. The *PCPA* also provides for broader reviews of the environmental and health risks of pesticides triggered by certain events. Section 17 of the Act provides that a special review is required where the Minister has reasonable grounds to believe that the health and environmental risks of a product are unacceptable or where another Organization for Economic Co-operation and Development country prohibits all uses of the active ingredient for health or environmental reasons.

19. Section 16 of the Act also provides for "re-evaluations" of registered pest control products. Re-evaluations are triggered by certain prescribed circumstances that allow the PMRA to address new information or scientific methods on pesticide risk, as well as cyclical reviews to be initiated 15 years after the registration of a new use or product.

20. Under section 16 of the Act the Minister may also initiate a re-evaluation of a registered pest control product if the Minister considers that, since the product was registered, there has been a change in the information required, or the procedures used, for the evaluation of the health or environmental risks or the value of pest control products of the same class or kind.

21. Under s. 19(1)(a) of the Act, during a re-evaluation the Minister may, by notice in writing, require the registrant to provide additional information that the Minister considers necessary for the evaluation (a data call). Subsection 19(1)(b) provides that the registrant has the burden of persuading the Minister that the health and environmental risks and the value of the pest control products are acceptable.

22. As with registration, under s. 19(2) the Minister shall apply a scientifically based approach in a re-evaluation. Specifically, under s. 19(2)(b)(i), the Minister must consider information on aggregate exposure to the pest control product, including dietary exposure, exposure from non-occupational sources (including drinking water) and cumulative effects from the product and products with a common mechanism of toxicity. Additionally, under s. 19(2)(b)(ii), the Minister must consider the use of animal experimentation data and the different sensitivities to the product of

major identifiable groups, including pregnant women, infants, children, women, and seniors.

23. In making the decision on cancellation, s. 20(2) requires the Minister to apply the precautionary principle, meaning where there are threats of serious or irreversible damage, the Minister shall not rely on a lack of scientific certainty to postpone cost-effective measures to prevent adverse health impact or environmental degradation.

24. Where the registrant fails to satisfy a requirement to provide information in a data call under s. 19(1)(a), the Minister may cancel or amend the registration pursuant to s. 20(1)(a).

25. Further, where the Minister does not consider that the health or environmental risks of the pest control product are acceptable following any required ~~a re-~~ evaluations, or consultations, the Minister shall amend or cancel the registration pursuant to s. 21(2).

26. Where the Minister amends or cancels a registration, the Minister may delay the effective date of the amendment or cancellation pursuant to s. 21(3) where there is no suitable alternative to the use available and the Minister considers that the health and environmental risks of the product are acceptable until the effective date of the amendment or cancellation. This delay is subject to any conditions that the Minister considers necessary for carrying out the purposes of the Act under s. 21(4).

27. When cancelling a registration the Minister may under s. 21(5) allow the continued possession, handling, storage, distribution and use of existing stocks of the product in Canada at the time of cancellation, subject to any conditions (including disposal procedures), that the Minister considers necessary for carrying out the purposes of the Act. The Minister may also require a recall or seize the product. Subsection 21(5) operates as a limited exception to the general prohibition on unregistered activities in s. 6(1) and does not allow activities such as transport or import that are permitted for registered products.

28. Where a registrant gives notice of intent to discontinue the sale of a pest control product for one or more registered uses, the Minister is required to cancel or amend the registration, as of a date to be determined by the Minister, and pending that date, the Minister may impose any conditions that the Minister considers necessary for carrying out the purposes of the Act under s. 22(3).

Re-Evaluation History of Chlorpyrifos

29. Chlorpyrifos is a notorious organophosphate pesticide. Organophosphates were first developed as toxic nerve agents for potential use in chemical warfare during World War II. Over the last two decades, scientific evidence has increasingly demonstrated that Chlorpyrifos likely causes brain damage in children and harm to infants *in utero*. This evidence includes evidence of Canadian environmental concentrations, use patterns and exposure levels.

30. Chlorpyrifos was first registered in Canada in 1969 for uses on various food crops including wheat, canola, corn, potatoes and other vegetable crops. It has also been registered to control insects in turf, ornamental plants, homes, commercial and farm buildings and for application to water bodies to control mosquitos.

31. Chlorpyrifos has become one of the most heavily used pesticides in Canada. It has frequently appeared in PMRA sales reports as one of the top ten insecticides sold by weight.

32. The PMRA initiated a re-evaluation of Chlorpyrifos and other organophosphate products in 1999 under the predecessor legislation to the modern *PCPA*. For more than two decades the PMRA failed to complete the re-evaluation. Instead of completing a comprehensive re-evaluation required by the Act, the PMRA broke it up into several constituent parts for different uses and different components of risk, resulting in an incomplete assessment of acceptable risk, with infrequent public updates or opportunities for consultation.

33. While PMRA delayed its assessment of the health and environmental risks and value of Chlorpyrifos, other international agencies such as the United States

Environmental Protection Agency ("**EPA**"), and the European Food Safety Authority ("**ESFA**") increasingly recognized the potentially serious health effects on children and infants through explicit and widely available risk assessments.

34. In 1999, when the re-evaluation was commenced, the PMRA explained that:

> The starting point for the Canadian re-evaluation of organophosphate pesticides will be the reviews being carried out by the EPA under the [U.S. *Food Quality Protection Act*] and will encompass those aspects covered by the EPA. The PMRA will be following in detail the EPA documents as they are published and will reassess this information in the context of the Canadian use situation. This will include a comparison with existing Canadian reviews/approaches and other international reviews and a survey of Canadian use/usage data to try to determine the significance of possible US actions, and the appropriateness to Canada of proposed risk mitigation measures.

The PMRA stated that the progress of these re-evaluations was highly dependent on the availability of EPA reviews. The target for completing the re-evaluation of all organophosphates was stated by the PMRA to be December 2000.

35. The PMRA completed a partial review of Chlorpyrifos data under the predecessor legislation to the *PCPA* in approximately 2000. As described by the PMRA, this review "mainly covered the non-agricultural uses (e.g. indoor and outdoor residential uses)." The PMRA also relied on data reviews and evaluations conducted by the EPA. This was later described by the PMRA as "phase one" of the re-evaluation. As a result of the EPA evaluations, manufacturers agreed with the EPA to discontinue certain uses. Several months later, the manufacturers agreed with the PMRA to discontinue residential uses and use on tomatoes.

36. The maximum residue limits ("**MRL**") of Chlorpyrifos permitted on foods for crops such as apples and grapes were also lowered. These changes were phased in over a one-year period. In the 2000 update on the re-evaluation of Chlorpyrifos, the PMRA stated that "Canada's re-evaluation of Chlorpyrifos will be completed to ensure that any required actions can be taken at the same time as in the United States."

37. In the 2000 re-evaluation update for Chlorpyrifos the PMRA stated that:

> Although the U.S. assessments have determined that the compound poses no imminent threat to public health, review of new animal data by the EPA suggests that fetuses may have an increased sensitivity to neurotoxic effects of chlorpyrifos. Given the new approaches to risk management now adopted by the PMRA and the EPA, which place specific emphasis on risk to children, an additional 10-fold safety factor is being applied to the existing 100-fold safety factor. This means that a 1000-fold safety factor will now be applied to chlorpyrifos, i.e., a person should not be exposed to any more than one thousandth of the level at which no effect occurs in experimental animals. The PMRA will adopt this conservative safety approach and limit the uses of chlorpyrifos accordingly.

38. In 2002 the EPA released a revised cumulative risk assessment for all organophosphates restricting some uses. Shortly afterwards, the PMRA released a re-evaluation note on organophosphates including Chlorpyrifos. The PMRA commented that it provided "substantial comment to the EPA on the December 2001 preliminary [cumulative risk] assessment and endorses the approaches taken in the revised [2002] assessment." This document stated that over the "next few months" the results of the EPA cumulative effects assessment would be assessed by the PMRA and stated that "[f]urther updates and details will be provided in the future as the Canadian cumulative risk assessment for [organophosphate insecticides] is finalized." To date the PMRA has still not finalized, nor is there evidence that it has even commenced, a cumulative risk assessment for organophosphate pesticides.

39. In 2003 the PMRA released a proposed Phase 2 risk assessment ("**Proposed 2003 Risk Assessment**") restricted to agricultural and forestry uses. The risk assessment was part of a cyclical 15-year initiation of re-evaluation commenced in 1999 under the predecessor to the modern Act. In the Proposed 2003 Risk Assessment, the PMRA declined to complete a cumulative assessment of organophosphate pesticides until re-evaluations of all the individual organophosphate active ingredients had been completed. Within the risk assessment the PMRA relied primarily on scientific information from Chlorpyrifos reviews conducted by the EPA.

40. Based on the PMRA's Proposed 2003 Risk Assessment which had again been conducted solely for agricultural and forestry uses, the PMRA found that there were no dietary health concerns for populations in Canada. However, the PMRA also

found there were significant gaps in field residue data, and that the PMRA did not have sufficient reliable monitoring data to quantify the risk from drinking water. The PMRA excluded drinking water from its conclusion that the short-term exposures do not exceed the PMRA's level of concern.

41. As a result of the Proposed 2003 Risk Assessment some uses were proposed to be discontinued on certain crops "for which there is little usage reported and for which non-[organophosphate] alternatives are registered" such as specific uses on pepper, sugar beet, filbert, lentils, oats and tobacco. For other uses labels were proposed to be amended for risk management.

42. The PMRA also noted in the Proposed 2003 Risk Assessment that it lacked data to establish safe MRLs for some domestic and imported commodities such as barley, canola, carrots, celery, garlic, onions, potatoes, strawberry and other food crops. In the interim the PMRA proposed to use "default" residue limits under the *Food and Drugs Regulations*. It stated "[h]owever, the PMRA intends to set specific MRLs for each treated commodity in Canada, and nullify the default MRL for chlorpyrifos." The document included data requirements for dietary risk and warned that if adequate data were not provided, the PMRA might be unable to recommend new MRLs and the sale of those commodities would not be allowed in Canada. The PMRA also noted that it lacked data for occupational and aggregate risk for some uses such as greenhouse ornamentals and mosquito fogging.

43. The PMRA stated in the Proposed 2003 Risk Assessment that it would refine the environmental risk assessment in the next phase of the re-evaluation "only on those actives, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, are acceptable from a human health perspective." The conclusion of the Proposed 2003 Risk Assessment was that effects on non-target organisms may occur, even for single applications at the lowest rates, and that Chlorpyrifos was acutely toxic at low concentrations.

44. In the Proposed 2003 Risk Assessment, the PMRA solicited comments on the continued registration of Chlorpyrifos products. It stated that it found the use of

Chlorpyrifos and end use products "does not entail an unacceptable risk of harm to human health or the environment… provided that the proposed mitigation measures described in this document are implemented." However, the PMRA did not finalize or implement the proposed restrictions on crop uses or the mitigation measures for workers at that time.

45. More than three years passed without any final decision to allow for implementation of ~~implement~~ the proposed mitigation measures. The modern *PCPA* came into force in 2006. In 2007 PMRA updated the public on its re-evaluation of Chlorpyrifos, including its proposed 2003 restrictions for human health. The 2007 update ("**2007 Re-Evaluation Update**") reversed the PMRA's proposed elimination of uses for a number of crops such as corn, filberts, lentils, oats, peppers, sugar beets, tobacco, peaches and nectarines. The stated rationale for this reversal was not acceptable risk, but rather "a variety of reasons relating to the value of the product" to growers.

46. In the comments on the 2007 Re-Evaluation Update, the PMRA noted the neurological development risks found in animal studies on pre-weaned pups and neonatal rats. The PMRA stated that the findings in these studies were "likely to correlate with that of postnatal development in humans. Thus, there remain considerable uncertainties in the extent of potential sensitivity and its relevance to the human child."

47. Within the 2007 Re-Evaluation Update, the PMRA described concerns regarding the high application rates when Chlorpyrifos is used on peaches and nectarines, as well as the difficulty in mitigating terrestrial and aquatic risks associated with this use. Similarly, PMRA concluded that "continuing registration of this use is acceptable in the short term, but will be revisited at the end of 2008 in light of the availability of any new alternatives and/or information." The PMRA acknowledged that its mitigation measures for mosquito larvicide use would not protect some organisms such as aquatic invertebrates and amphibians. The PMRA found other uses such as aerial spraying to also be a concern because potential effects

on terrestrial organisms, such as birds, were difficult to mitigate. The PMRA stated that while continued registration of these uses, as well as some other uses, would be permitted in the short-term, each of these concerns were slated to be revisited by the end of 2008.

48. In the 2007 Re-Evaluation Update PMRA also requested additional data for its ongoing human health risk assessment. There was a data call for drinking water monitoring data and environmental exposure levels for non-target wildlife, as well as for specific uses such as greenhouse ornamentals and mosquito fogging. This data was requested in 2007 even though data gaps for drinking water were identified four years earlier in 2003. The PMRA stated that "Model estimates for areas where cole crops are grown indicate that acute drinking water concentrations may be of concern."

49. Despite the PMRA's public commitment to finalize the environmental risk assessment in 2008, the PMRA fell silent. Neither the human health nor the environmental risk assessment portions of the re-evaluation were completed for Chlorpyrifos nor was the cumulative risk assessment of organophosphates initiated.

50. For over a decade the PMRA failed to complete the re-evaluation, to update the public on the content of its re-evaluation of Chlorpyrifos, and to publish any proposed decision.

Risks Posed to Human Health by Chlorpyrifos

51. Chlorpyrifos disrupts the functioning of acetylcholinesterase ("**AChE**"), a crucial enzyme that breaks down the neurotransmitter acetylcholine. This can result in harms to pregnant women, children and other vulnerable populations.

52. Separate and apart from the harm caused by acute AChE inhibition, studies since 2007 have increasingly demonstrated the risk that Chlorpyrifos might also be causing harm through a different mechanism leading to demonstrable chronic neurotoxic effects that are especially harmful to infants and children.

53. Beginning in the early 2000s the evidence of harm to human health from Chlorpyrifos began to become clearer, primarily through two kinds of studies: experimental studies on live mice and rats, and epidemiological studies tracking humans who were exposed to Chlorpyrifos in utero.

54. The EPA has consistently concluded that the available data support a conclusion of increased sensitivity of the young to the neurotoxic effects of Chlorpyrifos and for the susceptibility of the developing brain to Chlorpyrifos.

55. Between 2007 and 2016, the EPA published several Human Health Risk Assessments regarding Chlorpyrifos and convened its Scientific Advisory Panel ("**SAP**") several times. The EPA assessments and SAP reviews increasingly recognized the persuasiveness of the studies showing the risks of Chlorpyrifos to human health.

56. Each of the EPA risk assessments and related peer reviews concluded, relying on mounting evidence, that there were potential risks to human health. These risk assessments and peer reviews concluded that Chlorpyrifos was likely to cause harm with respect to neurotoxicity in children and infants in utero.

57. Since 2016 the EPA has proposed various actions on Chlorpyrifos but has not retreated from its conclusion that the residues of Chlorpyrifos on most food crops exceeds the reasonable certainty of no harm standard, the same standard applied under the *PCPA*.

58. Although the PMRA stated in its re-evaluation documents that it would be following the EPA evaluations closely and using many of the same criteria for its evaluations, from 2007-2019 the PMRA did not update its re-evaluation or impose new mitigation measures.

59. Three epidemiological studies (the "**Human Cohort Studies**") established a clearer basis for human health risk in the 2000s. In the Human Cohort Studies, researchers worked with a cohort of pregnant women and their children to collect data on the mothers' organophosphate exposure (including Chlorpyrifos) during

pregnancy. The researchers found a clear correlation between prenatal chlorpyrifos exposure and negative outcomes including cognitive impairments in early childhood.

60. In September 2008, the EPA convened a SAP to peer-review the EPA's findings. The 2008 SAP considered the results of the three Human Cohort Studies along with the findings from experimental studies in animals, and concluded that "maternal Chlorpyrifos exposure would likely be associated with adverse neurodevelopmental outcomes in humans." The SAP agreed with the EPA's conclusion that Chlorpyrifos likely played a role in the adverse birth and neurodevelopmental outcomes noted in the three Human Cohort Studies.

61. About three years later, in 2011, the EPA published a Preliminary Human Health Risk Assessment. The EPA discussed the three Human Cohort Studies and noted the 2008 SAP's conclusion that those studies, "in concert with the animal studies[,] indicate that 'maternal chlorpyrifos exposure would likely be associated with adverse neurodevelopmental outcomes in humans.'"

62. In April 2012, the EPA convened another SAP. The 2012 SAP opined with more certainty than the 2008 SAP that multiple "lines of evidence suggest that chlorpyrifos can affect neurodevelopment at levels lower than those associated with AChE inhibition, and that the use of AChE inhibition data may not be the most appropriate for . . . [assessing] the neurodevelopmental risks of chlorpyrifos."

63. Specifically, the 2012 SAP, based on its review of all the evidence available at the time, "concur[red] with the 2008 SAP and the Agency in concluding that chlorpyrifos likely plays a role in impacting the neurodevelopmental outcomes examined in the three cohort studies." It noted that the Human Cohort Studies showed potentially serious harms to infants and children, including "abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7–9 years, and attention and behavior problems at 3 and 5 years of age."

64. In December 2014, the EPA published a Revised Human Health Risk Assessment. It expressed greater certainty both that Chlorpyrifos was causing the

neurotoxic harms seen in the Human Cohort Studies and that it was doing so through a mechanism other than AChE inhibition. It stated that "[C]hlorpyrifos likely played a role in the neurodevelopmental outcomes observed in these epidemiology studies."

65. In November 2015, the EPA published a Notice of Proposed Rulemaking that proposed to revoke all Chlorpyrifos tolerances. Revoking tolerances would prohibit any residue being permitted on food products, meaning that pesticides containing Chlorpyrifos could not be used on food crops. To find that a tolerance is safe, the EPA must find it is reasonably certain that it will cause no harm.

66. In November 2015, the EPA published in the Federal Register a Notice of Proposed Rulemaking "proposing to revoke all tolerances for residues of the insecticide chlorpyrifos." The EPA wrote: "The agency is proposing to revoke all of these tolerances because [the] EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe."

67. The 2016 SAP concluded that "[B]oth epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell [AChE] inhibition."

68. In November 2016, the EPA revised its Human Health Risk Assessment again. The 2016 Revised Human Health Risk Assessment remains the EPA's most recent comprehensive assessment of the risks of Chlorpyrifos. In the assessment, the EPA "continue[d] to conclude that the [Human Cohort Studies] provide the most robust available epidemiological evidence."

69. The EPA "acknowledge[d] the lack of [an] established" mechanism of action that would explain the neurotoxic effects and also recognized "the inability to make strong causal linkages, and the unknown window(s) of susceptibility." The EPA concluded, nevertheless, that "[t]hese uncertainties do not undermine or reduce the confidence in the findings of the epidemiology studies. The epidemiology studies . . .

represent different investigators, locations, points in time, exposure assessment procedures, and outcome measurements." "In summary," the EPA concluded that "the [Human Cohort Studies] and the seven additional epidemiological studies reviewed in 2015, provides sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for AChE inhibition." Based on this finding, the EPA continued to conclude that it was necessary to adopt an approach "protective of both the AChE inhibition and any adverse effects that could occur at lower doses."

70. The EPA concluded that Chlorpyrifos tolerances were not safe – even considering food alone, without aggregating other exposure sources, like drinking water. For example, the EPA found in the 2016 Revised Human Health Risk Assessment that expected food exposure for children 1–2 years of age was 14,000% of the threshold level of risk concern. The EPA found that the tolerances it had established were "not sufficiently health protective".

71. In a 2016 Notice of Data availability the EPA concluded that "[E]xpected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard under the [Federal Food, Drug, and Cosmetic Act or FFDCA]…[The] EPA has not identified a set of currently registered uses that meets the FFDCA safety standard…"

72. The European Food Safety Authority (the "**EFSA**") reported in August 2019 on whether Chlorpyrifos should be renewed within the European Union. The EFSA reported that within a neurodevelopmental toxicity study, adverse effects in rats were observed at the lowest dose tested. These results, combined with epidemiological evidence on neurological outcomes in children, led the EFSA to conclude that a risk assessment cannot be safely conducted. On this basis the necessary approval criteria could not be met. The EFSA regulation directed the cancellation of Chlorpyrifos pesticides with a three-month phase-out for some products.

The PMRA's Work Since 2007

73. Although the PMRA claimed to be monitoring the EPA risk assessments for information on cumulative health risk assessments for organophosphates generally and for human health and environmental risks, the PMRA did not ~~act on~~ restrict uses or impose new mitigation measures based on any of the above updated risk assessments between 2008 and 2019.

74. The PMRA was aware, ~~or ought to have been aware,~~ of serious concerns about health risks from the EPA's 2016 risk assessment decision, as well as the decisions of other jurisdictions to cancel all uses of Chlorpyrifos.

75. Based on the issues raised in the EPA's risk assessments, as well as historical assessments conducted by the PMRA, the PMRA staff identified risks of concern from drinking water, mosquito adulticide and greenhouse uses, as a result of this the PMRA staff conducted further evaluations and requested data.

76. Because the PRMA's 2000-2003 assessment of dietary risk did not include aggregate risk from drinking water, the PMRA initiated and completed an analysis of drinking water risks from Chlorpyrifos, and to a lesser degree its metabolites such as oxon. The PMRA health reviewers concluded that Canadian environmental concentrations of Chlorpyrifos alone exceeded drinking water levels of comparison for certain populations. This exceedance indicated potential adverse health risks based on exposure of the Canadian population.

77. The PMRA failed to ensure that key data for human health such as inhalation data for mosquito fogging or residue data for greenhouse uses were provided by registrants after the 2007 Re-Evaluation Update. When, after several years the registrants failed to provide the data, the PMRA simply re-issued the data call-in in 2019.

78. On the basis of the missing information about adult mosquito fogging and assessed drinking water risks, the PMRA concluded that the risks of Chlorpyrifos were not acceptable. Internally, PMRA staff recommended the discontinuation of

mosquito adulticide and greenhouse uses and proposed notifying the public that drinking water exposure was unacceptable. However the PMRA did not notify the public.

79. On May 31, 2019 the PRMA issued Proposed Re-evaluation Decision PRVD2019-05, "Chlorpyrifos and Its Associated End-use Products: Updated Environmental Risk Assessment". This proposal related exclusively to the environmental risk assessment and proposed to cancel most outdoor uses of Chlorpyrifos due to environmental concerns. The concerns related to risks to beneficial arthropods, birds, mammals and all aquatic biota. Mosquito control, greenhouse uses and a few other uses, were proposed to continue with label requirement changes. These uses would be permitted to continue as a result of the environmental re-evaluation even though the registrants failed to satisfy the requirements of the 2019 data call-in.

80. The PMRA also stated in the Proposed Re-evaluation Decision that "[d]ue to recent international reviews", including those conducted by the EPA and EFSA, "new studies related to human health assessment have been generated, which, as indicated by various international jurisdictions, may inform the re-evaluation of Chlorpyrifos." Based on the relevant new information, the PMRA stated it would be updating the human health assessment and presenting it in a future publication.

81. The PMRA did not disclose publicly that it had already completed a dietary risk update for drinking water or that it was aware of dietary risks that were not acceptable under the existing use pattern for Chlorpyrifos. Further the PMRA did not disclose that it had concluded that the drinking water risks alone were not acceptable under current use patterns.

82. The PMRA also examined the drinking water risks under the reduced use patterns proposed in the proposed re-evaluation decision for environmental risk, which would not be implemented for several more years. The PMRA concluded that there would continue to be unacceptable risk from these reduced use patterns, once implemented. After further discussion, PMRA staff relied on assumptions about

whether the reduced use patterns would influence drinking water exposures to conclude that there was no unacceptable risk under the reduced use pattern.

83. On December 10, 2020 the PMRA issued the Final Re-evaluation Decision RVD2020-14, "Chlorpyrifos and Its Associated End-use Products (Environment)". Although this was a "final" re-evaluation decision on environmental risk, the PMRA made it clear that "the re-evaluation of Chlorpyrifos is ongoing" including for human health.

84. The PMRA in the Final Re-evaluation Decision proceeded to make four different decisions for different categories of uses to protect from environmental risk as follows:

(i) Uses requiring label amendments and new restrictions, which would require label amendments within a two-year implementation period;

(ii) Elm bark beetle control: uses continued;

(iii) Garlic and canola uses: delayed cancellation; and

(iv) Other outdoor uses: cancelled on a three-year phase-out.

85. Eleven organizations, including the Applicants, filed notices of objection under the *PCPA* requesting that the PMRA appoint a panel to review its conclusions in the environmental risk assessment. The objection also raises health concerns.

86. By the time of the Final Re-evaluation Decision, three of the registrants of the above products had already given notice to the Minister under section 22 of the *PCPA* that they intended to discontinue sale of the products. Within a few months of the Final Re-evaluation Decision, all of the remaining registrants had given notice of discontinuation.

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87. As of early June 2021 there are 24 Chlorpyrifos products listed in the Pest Control Products Registry as having active registrations. All of the registrations are listed as expiring in December 2023 or earlier. Many of these registrations are for uses on food crops, including canola and garlic, some are for mosquito control, structural uses, greenhouse uses or elm bark while others are for manufacturing uses, such as the formulation of another registered pest control product.

88. During the period between 2007 and 2021, the PMRA continued to renew the registrations of active Chlorpyrifos products that were subject to five-year expiry terms under the *Regulations*. The PMRA also registered new uses of Chlorpyrifos and new products that use Chlorpyrifos as an active ingredient. Based on the application date for the last renewal in the Pest Control Products Registry, the five year registration period for 10 of the products would expire before December 2023. Accordingly, the PMRA would need to renew these registrations under the *Regulations* to give effect to that expiry date.

89. At the time of the 2019-2020 environmental re-evaluation decisions, Health Canada indicated that the re-evaluation of the human health aspect was ongoing and was being updated. For example, within the Final Re-evaluation Decision, the PMRA noted that "some stakeholders called for a total ban of Chlorpyrifos based on recent international reviews…" In response, Health Canada would only say it is "aware of new scientific information cited in the recent international reviews" and that the PMRA would be updating the human health risk assessment.

90. On February 8, 2021 the Applicants filed their notice of objection to the Final Re-evaluation Decision.

91. On February 10, 2021, the PMRA finally took further public steps on the human health risk assessment. It issued a data call for toxicology data from two registrants, under s. 19(1)(a) of the *PCPA*. Much of the toxicology data requested was decades out of date. For example, the studies the PMRA requested dated from 1971,

1986, 1990, 2001, 2007, 2008 or 2010. The PMRA requested this data in 2021 even though the PMRA had been re-evaluating Chlorpyrifos for two decades, and had registered new uses as recently as 2017.

92. This data call-in notice was sent to two registrants who manufactured a total of six actively registered products. Between March and April of 2021 these two registrants issued notices of discontinuance of sale to the PMRA under section 22 of the Act for all six products. The registrants did not provide the data in the required 30 days. Three of these products were agricultural and could be used on a variety of crops such as strawberries, cucumbers, flax, canola, garlic and oats.

93. On April 29, 2021 the US 9th Circuit Court of Appeals required the EPA to propose a phase-out of Chlorpyrifos within 60 days.

94. On May 13, 2021 the PMRA issued Re-evaluation Note REV2021-02, "Update on the Re-evaluation of Chlorpyrifos" (the "**2021 Phase-Out Decision**"), through which it decided to cancel all Chlorpyrifos uses and products including those that remained registered following the environmental risk assessment under s. 20(1)(a) of the *PCPA*, citing the failure of the two registrants to provide data. In the 2021 Phase-Out Decision, the PMRA stated the re-evaluation for Chlorpyrifos is now considered complete. According to this decision, the existing stocks of all Chlorpyrifos products in Canada are being phased out with the following timelines:

- Last date of sale by registrant: 10 December 2021;
- Last date of sale by retailers: 10 December 2022; and
- Last date of use for all Chlorpyrifos uses/products including canola and garlic: 10 December 2023.

95. The PMRA stated in the 2021 Phase-Out Decision that "Health Canada has cancelled all chlorpyrifos uses/products." However, the PMRA's product information database provides a registration expiry date for most of these products of December

2023. Accordingly, it does not appear that the PMRA has "cancelled" these registrations.

96. In the alternative, if the PMRA did immediately cancel all the uses in February 2021, it did not include this information on the public registry. Nor did the PMRA require products being sold during the phase-out period to include labels with a specific expiry date or take any other measures under the applicable provisions of the *PCPA* to implement the cancellation of the product on a three-year phase-out or otherwise.

The PMRA acted unreasonably and without jurisdiction

97. The applicants challenge the decision to delay the effective date of the cancellation until December 2023, or to allow further use and sale of Chlorpyrifos products for three years after cancellation under section 21 of the *PCPA*. The applicants do not challenge the decision of the PMRA to cancel Chlorpyrifos registrations for failure to submit data under s.20(1)(a) of the *PCPA*.

98. The applicants acknowledge that the PMRA has discretion regarding the method of implementation of cancellations under s.21 of the *PCPA* where the criteria in that section is met, and the applicants acknowledge that the PMRA may do its own independent evaluations of exposure and risk separate from those in other jurisdictions. However, pursuant to the *PCPA* the PMRA is required to consider "available information" on hazards, exposure and risk, which includes information in the EPA and European assessments. The PMRA publicly committed to reviewing this information and coordinating or even aligning its reviews with those of the EPA. In this case, the hazards identified by the EPA and other jurisdictions resulted in the PMRA completing further exposure and risk analyses leading it to conclude that risks were unacceptable and/or that it could not determine acceptable risk.

99. The PMRA did not explicitly rely on any provision of the *PCPA* in allowing the existing stocks in Canada to continue to be sold and used for this three-year phase-out period. The PMRA did not provide any reasons or any risk management rationale for the phase-out. The PMRA's internal decision documents provide no

explanation for why the PMRA allowed the three-year phase-out. The PMRA lacked sufficient information and assessment of whether the phase-out would cause serious or irreversible harm to human health or cause otherwise unacceptable risks to human health.

100. The PMRA was aware of international reviews, including EPA reviews concluding that no levels of residue on foods were safe and that risk assessments could not safely be completed, resulting in the European Union ban in 2019. It was required to consider available information including this information in determining, under a "scientifically based approach", how to proceed with the cancellation of Chlorpyrifos as part of the re-evaluation.

101. In using a three-year phase-out in the 2021 Phase-Out Decision, instead of implementing the cancellation immediately, or imposing a requirement for disposal, recall or seizure of stocks of Chlorpyrifos, the PMRA unreasonably ignored the purpose of and constraints in the *PCPA* which required it to consider available information on the acceptability of health risks in determining whether to delay the effective date of cancellation, or ~~to~~ allow existing stocks to be used and distributed after cancellation, or require disposal and recall. The PMRA also failed to consider the potential risk that users would stockpile products during the phase-out.

102. Specifically, the PMRA acted unreasonably in ~~not evaluating whether the risks to human health posed by ongoing uses of Chlorpyrifos were acceptable in accordance with the *PCPA* for~~ allowing the three-year period during which the products would continue to be sold and used, including on food, given that the PMRA could not conclude that the health risks during the three year period were acceptable, since the PMRA had come to the conclusion that the risks were unacceptable.

103. The PMRA was unable to determine and/or lacked sufficient information or assessment to determine if the three-year phase-out of Chlorpyrifos use and sale presented acceptable risks. The PMRA was so lacking in reasonable certainty on acceptable risk that it determined that it had insufficient information on serious or imminent risks to the health of Canadians. The PMRA acted unreasonably and

contrary to the evidentiary onuses, acceptable risk standards, the primary objective of protection and the precautionary principle which are enshrined in the Act. In doing so, it unlawfully and unreasonably exposed Canadians, including pregnant women and infants at risk, of harm from Chlorpyrifos for three more years. ~~In the alternative, the PMRA relied on the incomplete status of its human health evaluations and applied a standard of imminent or serious risk to human health that is contrary to and counter to the fundamental purpose of the *PCPA* and the evidentiary onuses, acceptable risk standard and precautionary principle that are enshrined in the Act. In doing so it unlawfully put Canadians, including children and pregnant women at risk of harm from food and drinking water contaminated with Chlorpyrifos.~~

104. The PMRA has discretion under s.21 to order disposal or recall of Chlorpyrifos upon cancellation of the registrations of the active ingredient and end-use products where doing so would be consistent with the objectives of the *PCPA.* In failing to consider whether to do so the PMRA acted unreasonably. The PMRA fettered its discretion and further acted unreasonably by treating a three-year phase out as a default option. In doing so, the PMRA unreasonably failed to consider the scope and purpose of the discretion it was granted under s.21 of the *PCPA* and failed to exercise that discretion reasonably.

105. The PMRA ignored the relevant constraints under the *PCPA*, when permitting a phase-out and instead relied on the absence of ~~any~~ additional information on health risks from the data call-in to implement the three-year phase-out. The PMRA ignored relevant information it had on health risks from the EPA's 2016 risk assessment as well as prior EPA risk assessment determinations and determinations from other jurisdictions. The PMRA also ignored its own conclusions on drinking water risks based on Canadian use and exposure information. The PMRA concluded that it did not have current and up-to-date acceptable risk information on dietary risk, greenhouse uses and mosquito fogging.

106. The PMRA's prolonged phase out of three full years has the same practical effect as a delayed cancellation. In doing so, ~~it~~ the PMRA did not apply the

acceptable risk standard under the Act, it did not consider or apply the criteria in s. 21(3) of the Act, nor did it ensure that it imposed conditions on the cancellation that were necessary for carrying out the purposes of the Act under s. 21(5) or any other applicable cancellation provisions.

107. ~~Because~~ If the PMRA allowed 24 of the products to continue to be registered with expiry dates in December 2023, the PMRA effectively delayed the cancellation date through its 2021 Phase-Out Decision. The PMRA did not purport to apply, nor did the 2021 Phase-Out Decision comply with, the two pre-conditions in s. 21(3) of the Act or any other relevant constraints in the cancellation provisions of the *PCPA* when the PMRA delayed the effective date of the cancellations for three years. The PMRA did not find that no reasonable alternatives existed, nor did it find that the risks to human health were acceptable for the three-year period.

108. ~~In the alternative, if~~ If the PMRA did, in substance or in law, immediately cancel the registrations, it permitted existing stocks to be sold and used on a three-year phase-out under s. 21(5) of the *PCPA*. It did not impose conditions to prevent unacceptable risks or to protect human health from the sale, distribution and use of existing stocks for the three-year period, consistent with the risk avoidance and reasonable certainty of no harm objectives of the *PCPA*, as required by s. 21(5).

109. The PMRA also failed to ensure that any allowance of further sale and use included conditions necessary for carrying out the risk protection purposes of the *PCPA* as required under s. 21(5). The PMRA further acted unreasonably and without jurisdiction in allowing the continued sale of the products after cancellation, which is not authorized under s. 21(5).

110. The PMRA had a duty to publish reasons for the three-year phase-out period. The PMRA's 2021 Phase-Out Decision unreasonably fails to identify how the PMRA evaluated the risks to human health over the three-year period and how the phase-out would meet the harm prevention objectives of the *PCPA*, as well as the specific requirements of the cancellation provisions of the *PCPA*. The reasons provided by the PMRA for imposing the three-year phase-out period are not justified, transparent or

intelligible in relation to the statutory objectives of the *PCPA*, the criteria in s.21 of the PCPA, or the "available information" before the PMRA at the time of cancellation, and/or the PMRA's own conclusions about the information it had already considered.

111. If the PMRA failed to cancel the registrations, ~~T~~to the extent that the PMRA renewed or intends to renew some or all of the registrations until 2023, it failed to ensure the onus was met by the registrant to demonstrate acceptable risk under s. 7(6)(a) of the Act or that it had sufficient information under section 8 of the *Regulations* to renew the registrations. If that onus to demonstrate acceptable risk could not be met, the Minister is required to deny the renewals under s. 8(4) of the Act.

112. The Applicants are public interest litigants and have been advocating for the public's interest in environmental health and protection, and for urgent and responsible action to address the health risks of pesticides. The Applicants have raised issues of public importance in bringing this application for judicial review. An order pursuant to Rule 400 that no costs be awarded against the applicants is just and appropriate in the circumstances, in the event this Honourable Court sees fit to dismiss this application.

Jurisdiction and Additional Grounds

113. *Federal Courts Act*, RSC 1985, c F-7;

114. *Federal Courts Rules*, SOR/98-106;

115. *Pest Control Products Act*, SC 2002, c 28;

116. *Pest Control Product Regulations*, SOR/2006-124; and

117. Such further and additional grounds as counsel may advise and the Court may allow.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

118. An affidavit of ~~Charlotte Ireland~~ Elizabeth Gabel, to be served;

119. An affidavit of Elaine MacDonald, to be served;

120. An affidavit from a representative of each Applicant, to be served;

121. Material requested pursuant to Rule 317 and produced to the Applicants and to the Court pursuant to Rule 318 of the *Federal Courts Rules*; and

122. Such further and additional materials as counsel may advise and the Court may allow.

Rule 317 Request

123. The Applicants request that the Minister send a certified copy of the following material not in the Applicants' possession, but in the possession of the Minister, or the PMRA as the Minister's delegate, to the Applicants and to the Registry:

(a) All documents in the possession of the Minister, or the PMRA as the Minister's delegate, related to the evaluation of Chlorpyrifos for human health risks including but not limited to:

i. All correspondence, emails, meeting minutes, agendas, presentations, monographs, review memoranda, deficiencies reports, evaluation reports and other assessments of the human health risks of Chlorpyrifos prepared during the Chlorpyrifos re-evaluation, including but not limited to drafts and any documents to or from:

1. The re-evaluation review team;

2. The health evaluation directorate;

3. The science team lead;

4. The re-evaluation coordinator;

5. The Science or Health Management Committee or equivalent; or

6. The Registration Directorate or Chief Registrar;

ii. All monographs, draft monographs and peer reviews of monographs regarding the health risks of Chlorpyrifos;

iii. All copies of Science Management Committee or equivalent Committee Briefings, Presentations, Agendas and Minutes related to the PMRA's evaluation of the human health risks of Chlorpyrifos;

iv. All Science or Health Review Team memos or deficiency notes related to human health prepared during the re-evaluation of Chlorpyrifos;

v. All recommendations of the Science Review Team to the Science Management Committee related to the health risks of Chlorpyrifos prepared during the re-evaluation of Chlorpyrifos;

vi. All recommendations of the Health Evaluation Directorate and/or Science Management Committee to the Registrar concerning the health risks of Chlorpyrifos prepared during the re-evaluation of Chlorpyrifos;

vii. All applications to renew, amend, discontinue or register new uses for Chlorpyrifos and PMRA responses during the re-evaluation of Chlorpyrifos and related correspondence;

viii. All requests from the PMRA to registrants for human health data and registrant responses during the re-evaluation of Chlorpyrifos;

ix. The PMRA's May 13, 2021 decision to cancel all uses of Chlorpyrifos; and

x. Such further and other material as may be requested.

Date: ~~June 14, 2021~~ ~~October 20, 2021~~ February 10, 2022

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