Court File No. T-121-22

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC. and
PREVENT CANCER NOW

Applicants

- and -

ATTORNEY GENERAL OF CANADA and
MINISTER OF HEALTH

Respondents

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: January 20, 2022

Issued by: Todd Desanti
(Registry Officer)

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APPLICATION

1. This case is about Canada's pest management regulator, the Pest Management Regulatory Agency ("**PMRA**"), delaying 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**") to allow the sale and use of pest control products containing chlorpyrifos for a three-year phase-out period after all registrations and uses were cancelled.

3. Through a Re-evaluation Note published on May 13, 2021 ("**May 13, 2021 Decision**") the Minister purported to cancel all uses and registrations of chlorpyrifos and the registrations of registered end use products containing chlorpyrifos. 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. Through a Re-evaluation Note published on December 21, 2021, (the "**Amended Decision** or "**Decision**") the Minister purported to "replace" the May 13, 2021 Decision and to re-cancel four specific registrations of pest control products containing chlorpyrifos. Pursuant to subsection 21(5) of the *Pest Control Products Act* (the "**Act**" or "**PCPA**"), the Minister confirmed the three-year phase-out period for a number of products listed in Appendix I to that decision, and added two reporting conditions.

5. The decisions to allow the sale and use of chlorpyrifos over a three-year period following cancellation were unreasonable. The May 13, 2021 Decision was lacking in justification, transparency or intelligibility and without regard to the legal constraints under the PCPA. The Amended Decision was reverse-engineered to provide reasons to justify and "clarify" the May 13, 2021 Decision without regard to the legal and factual constraints faced by the Minister. In making the Amended Decision, the Minister misapprehended the evidence, ignored contrary findings by

PMRA scientists, denied the outcome or existence of prior scientific reviews by his own staff, and reverse-engineered a decision that would support the outcome. The Minister also ignored applicable statutory constraints relevant to the cancellation under sections 19-21 and 28 of the PCPA.

THE APPLICANTS MAKE APPLICATION FOR:

6. The Applicants make application for:

(a) A declaration that the Minister's decision to allow the continued sale and use of chlorpyrifos over a three-year period is unreasonable, unlawful and an error of law;

(b) A declaration that the Minister acted unreasonably and without jurisdiction in:

i. Permitting the continued sale and or/use of cancelled products without imposing disposal conditions necessary to carry out the purposes of the Act; and

ii. Permitting the continued sale and or/use of cancelled products without having completed a human health risk assessment in accordance with the required methodology prescribed by sections 19 and 20 of the Act;

(c) A declaration that the decision was unreasonable because the Minister failed to comply with the requirements of subsection 19(2) of the Act and associated risk assessment policies to assess whether continued use and sale posed acceptable risks;

(d) A declaration that the Minister erred in law in failing to consider the precautionary principle under subsection 20(2) when making the decision under subsections 20(1)(a) and 21(5);

(e) A declaration that the Minister unreasonably applied the serious and imminent risk standard and the phase-out period prescribed under the *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* without regard to the acceptable risk purpose of the Act, sections 19-21 of the Act or the incomplete status of the risk assessment;

(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 subsection 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 decision on 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.

Registration History of Chlorpyrifos

14. The Minister commenced the re-evaluation of chlorpyrifos in 1999. It released two prior decisions on the re-evaluation of chlorpyrifos in 2003 and 2007. In 2008 it put the re-evaluation on hold. From 2008 until 2019 the PMRA did not publish information for the public on the progress of the re-evaluation.

15. In 2019 the PMRA published a draft environmental-only risk assessment in the form of a proposed re-evaluation decision for chlorpyrifos. This was followed by a final decision in December 2020.

16. On December 10, 2020 the Minister published RVD2020-14, a final decision on the environmental risk assessment of chlorpyrifos which fully cancelled three registrations and cancelled a large number of outdoor and agricultural uses. These cancellations of both registrations and uses would take place on a three-year phase-out timeline allowing both sale and use ending in December 2023.

17. The environmental risk assessment decision also allowed a variety of uses such as elm tree, pine tree, greenhouse ornamental, outdoor ornamental, mosquito uses, and structural uses indefinitely for most chlorpyrifos registrations. Some registrations were also allowed to continue to be used on canola and garlic for specific uses for four more years under a delayed cancellation. These cancellations and use restrictions were based exclusively on the environmental risks posed by the cancelled or phased-out uses. All of this was explained in the public phase-out decision.

18. In the weeks subsequent to the December 10, 2020 environmental risk decision, some registrations of chlorpyrifos were voluntarily discontinued by registrants. These were also discontinued on the same three-year phase-out timeline ending in December 2023. The Minister did not notify the public about the three-year phase-out or the reasons for it. The Minister did not publish any public-facing document explaining which registrations were voluntarily discontinued, when or on what conditions at the time of cancellation.

19. In December 2020 the Minister also cancelled at least four registrations under subsection 20(1)(a) of the PCPA because the registrants did not respond to a 2019 human health data call-in issued as part of the re-evaluation. These registrations were also cancelled on a three-year phase-out allowing continued use and sale ending in December 2023. The Minister gave no reasons for this three-year phase-out and did not notify the public at the time.

20. In February 2021 the Minister issued a data call-in which requested a wide range of human health data cited in international reviews of chlorpyrifos. The data call-in was issued to two registrants who had a total of six registered products. The registrants did not provide the requested data in response.

21. On May 13, 2021 the Minister issued Re-evaluation Note REV2021-02, "Update on the Re-evaluation of Chlorpyrifos" ("**May 13, 2021 Decision**"), through which it decided to cancel all chlorpyrifos uses and products including those that remained registered following the environmental risk assessment under subsection

20(1)(a) of the PCPA, citing the failure of the two remaining registrants to provide data. The Minister stated the re-evaluation for chlorpyrifos was then considered complete. According to this decision, the existing stocks of all chlorpyrifos products in Canada would be phased out on the following timeline:

- 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.

22. The Minister stated in the May 13, 2021 Phase-Out Decision that "Health Canada has cancelled all chlorpyrifos uses/products." The May 13, 2021 Decision referenced all products that were not cancelled as a result of the final environmental risk decision. The May 13, 2021 Decision was the first notice to the public about any of the cancellations or phase-outs of the nineteen registered products whose registrations were not fully cancelled as a result of the final environmental risk decision or already cancelled at the time of that decision. The May 13, 2021 Decision did not provide any reasons for the three-year phase-out for the nineteen products and did not update the registry to indicate that any of the products were cancelled.

23. The Applicants filed a notice of application in Federal Court on June 14, 2021 seeking judicial review of the May 13, 2021 Decision, Court File No. T-956-21.

24. As a result of the Applicants' judicial review application, the Attorney General of Canada conceded on October 22, 2021 that the May 13, 2021 Decision was unreasonable due to a lack of reasons. On November 1, 2021 the Respondents advised the Court that "[a]s the Phase-out Decision did not give reasons for directing the three-year phase-out period, the Respondents acknowledge that the Phase-out Decision is unreasonable and must be set aside." Application T-956-21 has not yet been heard.

The Amended Decision

25. On December 21, 2021 the Minister published Re-evaluation Note REV2021-04, the Amended Decision. The Amended Decision confirmed that registrations of chlorpyrifos products would be cancelled "immediately" and that pursuant to section 21(5) of the Act, the use and sale of the product would be phased-out accordingly:

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

26. The Amended Decision purported to "replace" the May 13, 2021 Decision and to re-cancel "remaining chlorpyrifos products subject to the mandatory data call-in." The Decision states that the "remaining products" are cancelled "effective as of the date of this publication". The Amended Decision does not state if this is referring the February 10, 2021 data call-in for human health or the 2019 data call-in for human health, or both. Both data call-ins resulted in registrations being cancelled under subsection 20(1)(a) of the PCPA. The Amended Decision does not explain the basis upon which the Minister could cancel products that had already been cancelled in May 13, 2021, or how the cancellations could take effect at different times, almost a year apart.

27. The Amended Decision states that by the time of the February 10, 2021 data call-in, only four products from two registrants remained subject to the ongoing re-evaluation with respect to human health "because all other products containing chlorpyrifos were already in the course of being phased-out following prior cancellation decisions or following voluntary discontinuations." All products containing chlorpyrifos that are subject to a phase-out period are listed in Appendix I to the Amended Decision.

28. However, the wording of the Amended Decision in some places suggests that these reasons apply to all of the cancellations subsequent to the December 10, 2020 environmental risk assessment, or at least all the cancellations resulting from the two data call-ins. For example, the Minister's reasons describe the environmental risk assessment and then suggest that it applies to products cancelled after December 10, 2020: "In this current decision (REV2021-04), all remaining registrations of pest control products containing chlorpyrifos are cancelled immediately due to failure to fulfill the mandatory data requirements to update the human health risk assessment for the final phase of the re-evaluation." It is unclear whether the reasons provided apply to all the products being phased out, only products phased out for failure to provide data, or only the four products listed.

29. The Minister's reasons in the Amended Decision then provide that the Minister "confirms the cancellation of the registrations of the remaining products/uses of chlorpyrifos, and sets out Health Canada's determination that, in accordance with the *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* (the "***Policy***") the risks are not imminent and serious during the phase-out period."

30. The Amended Decision also adds two sales and incident reporting conditions that were not imposed in the May 13, 2021 Decision and clarifies that import and manufacture are not allowed during the three-year phase-out period.

31. Despite the ongoing litigation in T-956-21, and the Applicants' request that the Minister advise them about the timing and nature of the proposed second decision, the Minister did not advise the Applicants' counsel of the Amended Decision until 3:55 p.m. on January 14, 2022: six days before the limitation period expired.

Regulation of Pest Control Products in Canada

32. Subsection 4(1) of the Act provides that the "primary" purpose of the Act is the *prevention* of "unacceptable risks" to people and the environment from the use of pesticides. Acceptable risk is defined in subsection 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."

33. 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 subsection 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.

34. Under subsection 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.

35. Sections 16 and 17 of the Act also provide for post-market reviews called re-evaluations and special reviews. In completing those reviews, section 19 requires that the Minister apply a scientifically based approach to the re-evaluation and under subsection 19(2)(b) 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.

36. Under subsection 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-in). 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 in the course of the re-evaluation.

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

38. When cancelling a registration, the Minister may under subsection 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 subsection 6(1) and does not allow activities such as manufacture, transport or import that are permitted for registered products.

39. 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 subsection 22(3).

40. Public consultation is required pursuant to subsection 28(1)(b) where the Minister contemplates a decision “about the registration of a pest control product on completion of a re-evaluation or special review.”

The December 21, 2021 Decision is Unreasonable

The Amended Decision was made without jurisdiction

41. The Amended Decision purports to "replace" the May 13, 2021 Decision. However, the Amended Decision is not a new decision; rather, it simply provides an after the fact rationale for the May 13, 2021 Decision, which was not the basis for the original decision in the record at the time it was made in May 13, 2021. Additionally, the Amended Decision adds two reporting conditions.

42. To the extent that the Minister purports to re-cancel the registrations, or "replace" or "supersede" the May 13, 2021 Decision, the Minister was *functus officio* as a product registration can only be cancelled once. Further, reasons cannot be identified and provided after the fact for a decision that has already been made and given effect by the Minister when the Minister lacked any rationale for the decision at the time it was made. The Minister also lacked jurisdiction to "re-cancel" registrations which no longer existed.

The PMRA ignored key legal constraints

43. To the extent the new reasons in the Amended Decision apply or might apply to the decision on the phase-out as a whole – including both the original May 13, 2021 Decision and Amended Decision – the decision as a whole is unreasonable. The Amended Decision reverse-engineers a risk management rationale to justify the existing three-year phase-out. The PMRA failed to apply a "scientifically based" approach required during a re-evaluation under subsection 19(2)(a) of the PCPA, and failed to consider the factors under subsection 19(2)(b): aggregate risks from drinking water or cumulative effects of exposure to chlorpyrifos with other organophosphates.

44. Under subsection 19(1)(b) and (c) of the PCPA, the burden is on the registrant to persuade the Minister that the risks posed by continued use and sale during the phase-out are acceptable. The decision on the phase-out is a decision made on the completion of the re-evaluation process, and the requirements of the re-evaluation process are applicable. The Minister's Decision ignored this onus on the registrants

by ignoring the failure of the registrants to submit data in response to the human health data call-in. The Minister instead treated the burden as being on the PMRA to establish serious and imminent risks under the *Policy*.

45. The Minister misapprehended the evidence of PMRA scientists in a fundamental way. The Amended Decision was made in a perverse and capricious manner and based on erroneous findings of fact and without regard to the material before the Minister. The Amended Decision is not transparent, intelligible or justifiable in relation to the PMRA's own risk assessment policies or the prior findings of PMRA scientists.

46. The Minister ignored his own policies on how to conduct risk assessment analysis, in particular in the context of dietary risk and drinking water risks. Instead of following the process for risk assessment in these policies, and the prescribed considerations under section 19 of the Act, the Minister cherry-picked particular information that appears to support a conclusion of low human health risk.

<u>The Minister's reasons contradict PMRA scientists' findings on the relevance and importance of foreign reviews to the human health risks of chlorpyrifos</u>

47. In the Amended Decision, the Minister repudiates the relevance or significance of material it had previously used as part of the basis for the underlying cancellation. As such the Minister's decision is unreasonable as it fails to accord with applicable factual constraints.

48. For example, PMRA scientific staff identified hazards from the prior US Environmental Protection Agency ("**EPA**") and European Food Safety Authority ("**EFSA**") assessments. In light of the EPA and EFSA assessments, the PMRA determined they needed to better understand genotoxic potential, developmental neurotoxicity, establish appropriate toxicological endpoints and other issues in order to complete the Canadian human health risk assessment.

49. In order to develop the 2019 and February 10, 2021 data call-ins, the PMRA relied heavily on the prior EPA and EFSA assessments. The PMRA requested that

registrants provide the same data that those agencies relied on in their assessments of the hazards and risks posed by chlorpyrifos, as identified by those agencies. This data was then *required* under subsection 19(1)(a) of the PCPA. The failure to provide this data led to the underlying cancellation in both the May 13, 2021 and December 21, 2021 decisions under subsection 20(1)(a) of the PCPA. As a result of the failure of registrants to submit the data, the PMRA was unable to complete its human health risk assessment.

50. The reasoning provided for the phase-out in the Amended Decision is fundamentally inconsistent with the underlying cancellation decision. The reasoning in the Amended Decision concludes that the findings of prior EPA or EFSA assessments are not relevant to its risk findings in the Canadian context because they are not based on Canadian use patterns or application rates. In other parts of the Amended Decision, the PMRA concludes that these assessments taken alone, without data on the Canadian context and without access to the underlying data that they requested in the data call-in, demonstrates that there are no serious or imminent risks. Yet, the burden was on the registrant under section 19 of the Act to provide this information, without which the PMRA could not complete its human health risk assessment. In this regard the Amended Decision and the decision as a whole, inclusive of the May 13, 2021 Decision is unreasonable on the facts and unreasonably ignores the legal constraints in sections 19 and 20 of the Act.

51. The Amended Decision lacks justification, transparency or intelligibility in light of the Minister's characterization of the EPA and EFSA reviews. The Minister does not explain why its scientists would request irrelevant data it did not need, and would proceed to cancel the products when it was not received if the data was not needed to inform human health risks. The Amended Decision does not explain how the PMRA could have reasonable certainty that no harm would occur during the phase-out period without this data. The Amended Decision considers irrelevant issues, such as whether the EPA and EFSA reviews taken alone, without a complete human health risk assessment in the Canadian context, demonstrate that there is serious or imminent risk.

The Minister ignored key conclusions of unacceptable risk of PMRA scientists on reference doses and drinking water

52. PMRA scientists relied on a 2014 EPA risk assessment to conclude that they needed new toxicological endpoints for chlorpyrifos oxon, a more toxic metabolite that is derived from chlorpyrifos when exposed to chlorine in drinking water. Chlorpyrifos oxon had not previously been addressed by any PMRA risk assessments. The PMRA has no toxicological endpoints or reference dose for chlorpyrifos oxon. As a result of the conclusions of the 2014 EPA risk assessment, the PMRA conducted a detailed and refined modelling of estimated environmental concentrations of chlorpyrifos in Canada based on Canadian drinking water data, use patterns and application rates.

53. The PMRA then compared the modelled concentrations to drinking water levels of concern which reflected whether the reference dose would be exceeded for chlorpyrifos alone based on Canadian diet. The conclusion of this modelling in 2016 and further refined modelling in 2017 was that under the current use patterns – patterns which can continue until December 2023 – the drinking water levels of comparison used to establish unacceptable risks were exceeded. This modelling used and relied upon available drinking water monitoring data. The PMRA scientists concluded that monitoring data showing exceedances of the drinking water level of concern was appropriate for use in modelling, and that drinking water levels of concern were exceeded based on the models. This resulted in a finding that chlorpyrifos posed unacceptable risks from drinking water by PMRA toxicology staff.

54. The Amended Decision seemingly denies that the refined drinking water modelling ever occurred. The Amended Decision states that “a fully updated assessment for drinking water has not been completed in Canada…”. In suggesting that the drinking water assessment had not been done, and ignoring the evidence and conclusions from its own scientists based on drinking water modelling, the Minister misapprehended the evidence and ignored key evidence in relation to drinking water risks. The Amended Decision also lacks transparency and intelligibility in this regard.

55. Further, the Minister's reasons in the Amended Decision states the opposite conclusion from those of PMRA scientists, stating that there is a low level of concern for chlorpyrifos breakdown products including chlorpyrifos oxon since chlorpyrifos is "unlikely" to be found in drinking water sources. The PMRA's own modelling, which the Minister now denies occurred, led its own scientists to conclude the opposite.

56. Instead of assessing risk in accordance with its risk assessment policies, which use both modelling and monitoring data, and compare the aggregate risks of dietary and drinking water exposures as required by section 19 of the Act, the Amended Decision cites drinking water monitoring data alone to speculate that there is low risk. This method, of assessing risks without regard to the precautionary principle, without establishing a reference dose, without estimating environmental concentrations, without utilizing uncertainty factors, and without taking into account aggregate risk from diet is contrary to PMRA policy and sections 19 and 20 of the PCPA. Policies that the PMRA ignored, sidestepped or contravened in assessing the risks of a three-year phase-out include but are not limited to DIR2016-04, SPN2008-01, DIR2001-03, SPN2003-03, SPN2004-01, SPN2003-04, and the 2021 *Framework for Risk Assessment and Risk Management of Pest Control Products*.

Minister ignored PMRA's conclusions that toxicological end-points were out of date

57. Further, the Amended Decision ignores the conclusion of PMRA's own scientists from only a few months prior that toxicological endpoints or reference doses needed to be revisited and revised. PMRA staff repeatedly concluded that the reference doses required revision between 2015 and 2021. They also concluded that further data was required to address this issue and assess the risks of chlorpyrifos in diet and drinking water. In failing to consider these conclusions reached by PMRA scientists explicitly, the Minister acted unreasonably.

58. Between 2015 and 2021 PMRA scientists extensively discussed whether the dietary (food only) risk assessment completed in October 2000 and relied upon in the PMRA's 2003 and 2007 human health risk assessments needed to be updated as well

as whether toxicological endpoints needed to be reviewed. They found repeatedly that the dietary risk assessment was not reliable and needed to be updated. They also stated as late as February and April of 2021 that the assessment of dietary risks had never been updated to reflect current use patterns, to address most recent residue and monitoring data or to address transformation products or toxicology reference value revisions that might be needed. PMRA science staff also concluded that the dietary risk assessment needed to be updated to consider exposure from imported treated foods. They concluded that the current dietary risk to Canadians was "unknown" and could be underestimated if relying on the 2000 dietary risk assessment.

59. The Minister's Amended Decision, made only a few months later, states the opposite. It states that "[p]otential dietary exposure and risks from chlorpyrifos have also been considered based on **current** Canadian registered uses" (emphasis in original). To the Applicants' knowledge, no dietary risk assessment has ever been conducted in compliance with PMRA policy based on current Canadian use patterns including expanded uses since 2000. The Minister has completely misapprehended the evidence in citing an updated dietary risk assessment based on current use patterns that does not exist.

The Minister ignored PMRA scientists' conclusions on higher residues

60. Similarly, in April 2021 PMRA scientific staff reviewed Canadian Food Inspection Agency monitoring data from 2013-2017 and concluded that this pointed to "higher potential residues" that were "significantly higher than those used in the 2000 [dietary risk assessment]." They also pointed to higher percentage of crops treated as a concern that they stated made the 2000 dietary risk assessment out of date. Numerous PMRA documents dating back to 2003 discuss the lack of sufficient residue information for chlorpyrifos.

61. The Amended Decision provides no transparent, intelligible explanation for the Minister's failure to consider the higher potential residues highlighted by the PMRA scientists, and instead focuses on the frequency of detection alone.

62. The Minister ignored the warnings of PMRA scientists about the potential effects of higher residues demonstrated by this same data. In the Amended Decision, the Minister focuses solely on the *frequency* and whether this lower *frequency* of detection is consistent with the 2003 re-evaluation proposed decision (which relied on the 2000 dietary risk assessment). The Minister reverse-engineered the Amended Decision by ignoring conclusions of PMRA scientists about how this same data points to higher residues, making the same prior assessments of dietary risk out of date and unreliable. In ignoring the evidence of higher residues which its own scientists concluded made the existing dietary risk assessment unreliable, the Minister acted unreasonably and misapprehended the evidence in and arbitrary, perverse and capricious manner.

63. The Minister's conclusion that there is "low health concern from food" relies exclusively on the 2000 dietary risk assessment that PMRA staff found was out of date, and which did not consider the aggregate risks from diet and drinking water, cumulative effects, and did not used a scientifically based approach or precautionary approach required under sections 19 through 21 of the PCPA. In allowing continued use and sale without an updated dietary risk assessment the Minister postponed measures to prevent unacceptable risks based on uncertainty. In doing so the Minister acted unreasonably.

<u>The Minister failed to consider human health risks raised in the notice of objection</u>

64. The Minister also unreasonably failed to address the health risks raised in the applicants' notice of objection to the environmental risk assessment including that chlorpyrifos contributes to multiple chemical sensitivities and that the occupational risks posed to people working in industrial structures is unknown. The Minister did not respond to the notice of objection, nor did the Minister address these risks in the May 13, 2021 Decision or the Amended Decision.

Minister failed to consider complete absence of data supporting continued greenhouse and mosquito uses

65. The PMRA requested data from registrants in 2003 and 2007 related to the human health (occupational risk) aspects of greenhouse and mosquito adulticide uses. These data requests would be repeated several times between 2003 and 2021, and PMRA scientists concluded that the data submitted was insufficient to support these uses, and repeatedly recommended that these uses be cancelled.

66. Instead of cancelling the uses the PMRA would simply repeat the data call-ins, including in 2019 and continued to permit the greenhouse and mosquito adulticide uses after the environmental risk assessment. These uses continue to be allowed for several registrations until December 2023.

67. The Amended Decision does not address potential occupational risks from mosquito adulticide or greenhouse uses during the phase-out period and unreasonably and unlawfully ignores occupational risks.

The Minister failed to adhere to the statutory constraints on his discretion

68. The Minister cannot evade the requirements to assess risks using the prescribed methods under subsections 20(2) and 19(2) of the PCPA and associated policies simply by discontinuing the human health re-evaluation for lack of data. Subsection 19(2) requires the assessment of risk using a scientifically based approach that assesses the aggregate risks of diet and drinking water as well as the cumulative effects with other organophosphates. The Minister failed to apply this approach to the assessment of risks of the phase-out period that flowed from the completion of the re-evaluation.

69. The Minister failed to assess the risks posed to human health by the phase-out period. The Minister also failed to consider conditions necessary to carry out the purposes of the Act under subsection 21(5)(a). In conducting an analysis of potential risks, the Minister failed to do so in accordance with the requirements of subsections 19-20 of the PCPA. These sections reflect Parliament’s intentions regarding the

methodology for assessing the purposes of the Act under subsection 21(5)(a). In ignoring these requirements, the Minister acted unreasonably and unlawfully and contrary to both the purposes of and prescribed scheme of the Act.

70. In sum, the Minister ignored the applicable factual and legal constraints on its Decision set out in sections 19-21 of the Act. It reverse-engineered a rationale that would permit it to "confirm" its existing three-year phase-out. Further, the Minister ignored the PMRA's own policies on risk assessment methodology for determining and assessing human health risks. Finally, the Minister ignored the legal constraints under subsection 2(2) and sections 19-21 of the PCPA, which required the PMRA to conduct a scientifically valid assessment of risk when implementing a cancellation.

71. In cancelling the products under subsection 20(1)(a) and allowing continued use for three more years, despite the uncertainty around potential human health risks resulting from an incomplete evaluation and the fact that the health risks were largely unknown, the Minister erred in law.

72. When exercising discretion under subsection 21(5)(a) of the Act where important data on human health was not provided by a registrant, the Minister did not consider the cancellation conditions necessary to best achieve the purposes of the Act. The "primary" purpose of the Act is to prevent unacceptable risks, meaning there is reasonable certainty of no harm. An ancillary objective is to minimize health and environmental risks posed by pest control products. In selecting the method of implementation for the phase-out, the Minister must consider the conditions necessary to achieve the purpose of preventing or minimizing risk. The Minister failed to do so.

73. The Minister further erred in law under subsection 21(5) by not imposing disposal conditions. Disposal conditions are mandated by subsection 21(5)(a) where the Minister allows continued possession, handling, storage, distribution and use.

The Minister's reasons are not rational, transparent or intelligible

74. In light of the contrary analysis and findings of PMRA scientists, and methods set out in PMRA policy, the Minister's decision is not rational, transparent or intelligible. As described above, the Minister ignored key factual constraints, including strongly worded conclusions of the PMRA scientists from only a few months prior, that was highly unfavourable to the method he selected for implementing the cancellation. The Minister instead only addressed evidence – or the absence of evidence – that was favourable to the desired outcome. The Minister unreasonably relies on evidence which does not exist, such as an up-to-date dietary risk assessment based on current uses, and denies or ignores the existence of a drinking water assessment finding unacceptable risk to support the Amended Decision.

75. The decision as a whole and the Amended Decision specifically further lacks transparency, rationality or intelligibility in relation to the purposes of subsection 21(5) of the PCPA and the Act's "primary purpose" of preventing unacceptable risks. This provision gives the Minister broad discretion to determine how to implement a cancellation. However, it requires that the Minister turn his mind to the purposes of the Act when relying on subsection 21(5)(a). Further, the Minister must consider the purposes of the Act under subsection 21(5)(a) in light of the prescribed methods in sections 19 and 20 of the PCPA.

76. The Minister fails to explain transparently and intelligibly why three full years of continued use, with no disposal conditions, is a "necessary condition" in light of the primary purpose of the Act. The only explanation in the Amended Decision for the specific phase-out period imposed by the PMRA under the *Policy* is that it allows existing stocks to be exhausted in an orderly manner, to minimize potential risks associated with disposing of existing product all at once and to minimize confusion for the users.

77. The Minister also fails to explain in a transparent and intelligible manner how he can justify three full years of continued use when PMRA has not conducted a valid

scientifically based assessment of risks but has instead cancelled chlorpyrifos because of a failure to provide data or to establish the risks were acceptable for the three-year phase out period.

78. To the extent the Minister does consider minimization of risks from "disposal all at once" the Minister does not explain if there is indeed a risk, or what that risk is, from disposal all at once or why allowing continued sale and use of stocks for several more years is the only or best way from the perspective of risk minimization. As such the Minister's reasons lack justification, transparency and intelligibility. The failure of the Minister to turn his or her mind to conditions that might better minimize risks flowed from the Minister's unreasonable and unscientific analysis that the risks were low.

79. The Minister's reasons fail to establish that the risks were acceptable for the period of the phase-out. The Minister was unable to establish this because the human health risk assessment was never completed. The Minister acted unlawfully and misapprehended the evidence in determining that the largely unknown risks of chlorpyrifos were not serious and imminent in the absence of a completed risk assessment.

80. The Minister's reasons also lack justification, transparency and intelligibility as they fail to explain how two more years of sale and three more years of use meets the risk prevention objectives of the PCPA overall. In particular, the Minister fails to explain why the stated goal of phased disposal could not have been achieved with permission to possess instead of sell and use, combined with a clear condition to dispose of product at the end of each relevant phased period. The Minister references avoiding confusion for the users, but does not link this to any human health risk that might materialize from such confusion. The Minister cites no evidence that a different phase-out approach would cause such confusion.

81. The reasons, read in light of the record as a whole, are also lacking in transparency and intelligibility. The reasons are unclear as to the Amended Decision's scope and status relative to the May 13, 2021 Decision. The Amended

Decision does not clearly explain what cancellations the reasons apply to. The Amended Decision does not explain to the public when the cancellations actually took place, what products were cancelled, or what uses are permitted for each product during the three-year phase-out.

The Minister fettered his discretion

82. The Minister also erred in law in effectively treating the three-year phase-out period as mandatory under the *Policy*. The Minister's reasons provide that "[i]n cases where no imminent and serious risks to human health or the environment are identified, the implementation timelines outlined in [the *Policy*] **are applied**" (emphasis added). It further states that the PMRA **does not** impose other conditions such as recall unless there are "adverse effects reported in incident reports submitted to Health Canada involving death or serious bodily harm." This interpretation of the *Policy*, requiring the Minister to permit continued sale and use unless they have evidence from or on behalf of an actual victim that this would result in death or serious bodily harm, is not consistent with the primary purpose of the *Act* and unreasonably fetters the Minister's discretion.

83. The Minister erred by failing to consider whether the application of the *Policy* was appropriate in light of the risk prevention and precautionary scheme of the Act. Specifically, Minister erred by failing to consider whether it was appropriate to rely on the *Policy* in a situation where the human health risk assessment was never completed. The Policy does not address the primary purpose of the Act in preventing unacceptable risks and therefore does not relieve the Minister from the requirement to consider potentially unacceptable risks. The *Policy* presupposes that the Minister has sufficient information on human health risks to demonstrate that the phase-out period does not pose unacceptable risks in light of the primary purpose of the Act.

84. Subsection 21(5)(a) is discretionary, it *permits* but does not *require* the Minister to continue to allow use of the existing stocks at the time of cancellation. Where the Minister relies on subsection 21(5)(a), the exercise of discretion must be subject to any conditions the Minister considers necessary *for carrying out the*

purposes of the Act, the primary purpose of the Act being the prevention of unacceptable risks. The reporting conditions imposed by the Minister would merely inform the Minister of increased risks after the fact and cannot satisfy the criteria in this section.

85. The *Policy* also does not relieve the Minister of the obligation to consider the conditions necessary to prevent unacceptable risks, including disposal conditions. It also cannot render subsection 21(5)(a) mandatory. In other words, the *Policy* cannot be treated as a *carte blanche* requiring the Minister to allow further sale and use on the basis that no one has reported serious bodily harm or death in an incident report.

86. To the extent that the reasons conclude per the *Policy* that there are no serious and imminent risks from chlorpyrifos – to the extent that it addresses the level of risks – the Minister ignored the factual constraints that were binding on the Minister in making that decision. The Minister also ignored the legal constraints requiring a scientifically based approach that considered aggregate and cumulative risks as well as uncertainties in the incomplete and out of date human health risk assessment.

87. The Minister failed to consult the public as is required under section 28(1)(b) about the proposed phase-out. The Minister was making a decision about the registration of a pest control product on the completion of a re-evaluation. The PMRA has repeatedly actively avoided advising the public of its adverse findings about dietary risk and drinking water for chlorpyrifos. The decision as a whole failed to accord with the legal constraints in section 28(1)(b) and is therefore unreasonable.

88. The Amended Decision demonstrates a failure to consider factual constraints, namely the findings of PMRA scientists and staff on acceptability of risk, is not compliant with the statutory scheme and purposes of the Act. The reasons for the Amended Decision are therefore not justified, transparent or intelligible. Instead, the Amended Decision is designed to reverse-engineer the Minister's preferred outcome, to provide supplementary reasons to the May 13, 2021 Decision which the PMRA has already conceded to be unreasonable, and to pre-empt the setting aside of the May 13, 2021 Decision.

89. 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

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

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

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

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

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

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

95. An affidavit of Elizabeth Gabel, to be served;

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

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

98. 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

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

Rule 317 Request

100. 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. All analysis of drinking water monitoring data, estimates of environmental concentrations of chlorpyrifos in drinking water, and comparisons of estimated environmental concentrations of chlorpyrifos with drinking water levels of concern prepared for chlorpyrifos since 2007;

x. All assessments of dietary risk for chlorpyrifos prepared since 2000.

xi. The PMRA's May 13, 2021 Decision to cancel all uses of chlorpyrifos;

xii. The PMRA's December 21, 2021 Decision to cancel all uses of chlorpyrifos; and

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

Date: January 20, 2022

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