Court File No. T-169-23

FEDERAL COURT

BETWEEN:

FRIENDS OF THE EARTH CANADA, DAVID SUZUKI FOUNDATION, SAFE FOOD MATTERS INC., and ENVIRONMENTAL DEFENCE CANADA INC.

Applicants

- and -

ATTORNEY GENERAL OF CANADA, MINISTER OF HEALTH and LOVELAND PRODUCTS CANADA INC.

Respondents

WRITTEN REPRESENTATIONS OF THE APPLICANTS (MOVING PARTIES)

OVERVIEW

1. This is a motion under Rules 317 and 318 of the *Federal Courts Rules* for the production of the certified record. The certified record that has been produced is incomplete and will not allow for a meaningful judicial review of the decision being challenged.

2. The application is a judicial review of the Pest Management Regulatory Agency ("**PMRA**") decision to renew the registration of the pest control product "Mad Dog Plus" under s. 7 of the *Pest Control Products Act* (the "**Act**"). The application alleges the decision was unreasonable because the PMRA failed to update its health and environmental risk assessment of glyphosate, the active ingredient in Mad Dog Plus. Given this failure, the Minister could not have had reasonable certainty, as required by the Act, that no harm to

human health and the environment would result from exposure to or use of the product, and therefore the renewal of the product registration was unreasonable.

3. The certified record is incomplete because it does not provide the reasons or rationale for the decision. The record provides memoranda concluding that 61 pieces of new science on the health and environmental risks of glyphosate do not change the PMRA's prior risk assessment for Mad Dog Plus. However, the record does not provide any reasons or any insight into the reasoning process for this conclusion.

4. The PMRA is required under the Act to conduct a "scientifically based" assessment of risk and to conclude, in accordance with the standard in the Act, that there is reasonable certainty that no harm will occur to human health and the environment. Without the scientific analysis leading to the conclusion, the applicants and this Court cannot ascertain whether the decision was reasonable. Accordingly, the requested material should be produced.

PART I – FACTS

5. The underlying application for judicial review challenges the decision of the Minister of Health, through the PMRA, to renew the registration of a pest control product called "Mad Dog Plus". The applicants assert that this decision was unreasonable because the Minister failed to comply with the requirements in the *Pest Control Products Act*[1] and the *Pest Control Products Regulations*[2]. These require the PMRA to assess the health and environmental risks of a pest control product and to conclude, using a scientifically based

[1] *Pest Control Products Act*, SC 2002, c. 28 [**PCPA**].
[2] *Pest Control Products Regulations*, SOR/206-124 [**Regulations**].

assessment, that there is reasonable certainty that no harm will occur from use or exposure to the product.[3]

The Renewal Decision

6. Mad Dog Plus (the "**Product**") is a pest control product containing the active ingredient glyphosate and has been registered for use in Canada since 2011.[4] Glyphosate has been registered in Canada since the 1970s and is the most heavily used pesticide active ingredient in Canada.[5] The Product's registration was set to expire December 31, 2022.[6] The registrant (the respondent Loveland Products Inc.) applied to renew the Product's registration in August 2022.[7] On December 22, 2022, the PMRA renewed the Product's registration for another 5-year term.[8]

7. Prior to the renewal decision, in October 2022, the applicants wrote to the PMRA requesting that no renewals of products containing glyphosate be granted until the PMRA reviewed and considered up-to-date science concerning the human health and environmental risks of glyphosate.[9] The PMRA's most recent risk assessment of

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[3] *PCPA*, ss. 2(2), 4(1), 7, 8; Regulations, ss. 6, 8, 16.
[4] Notice of Application at para 23, MR Tab 5, p. 2022.
[5] Affidavit of Beatrice Olivastri, affirmed May 4, 2023 [**Olivastri Affidavit**] at paras 5, 8, Motion Record [**MR**] Tab 3, pp. 574, 575.
[6] Notice of Application at para 23, MR Tab 5, p. 2022.
[7] Affidavit of Charlotte Ireland, affirmed April 28, 2023 [**Ireland Affidavit**], Exhibit D (CTR Doc 4: Application for Renewal or Discontinuation under the *Pest Control Products Act* dated August 9, 2022), MR Tab 2, p. 477; Notice of Application at para 24, MR Tab 5, p. 2022.
[8] Ireland Affidavit, Exhibit D (CTR Docs 13 and 14: Email dated December 28, 2022 from A. Ahmed on behalf of PMRA Renewal to A. Preradov attaching Renewal Registration Certificate), MR Tab 2, pp. 504-505.
[9] Ireland Affidavit at para 3 and Exhibit A (Letter dated October 27, 2022 from L. Bowman to F. Bissonnette), MR Tab 2, pp. 8-9, 13; Olivastri Affidavit at para 9, MR Tab 3, p. 575.

glyphosate had taken place during its re-evaluation[10] of glyphosate, which was finalized in 2017.[11] Since that time, there has been significant new science demonstrating new or increased risks from exposure to or use of glyphosate.

8. The applicants' October 2022 letter identified a range of new research relevant to the risk assessment of glyphosate, including regarding human health – effects on the microbiome (gut microflora), carcinogenicity, neurodegenerative and reproductive toxicity – and environmental risk – adverse impacts to pollinators and exposure to pollinators, including to monarch butterfly habitat, and ecological harms to freshwater ecosystems.[12] The applicants cited 61 new scientific documents, many of them published, peer-reviewed studies, which indicated new or increased human health and environmental risks that were not previously considered by the PMRA.[13]

9. The PMRA responded to the applicants in February 2023, after having already renewed the Product's registration and after the applicants commenced this application, noting that the PMRA was "aware of the scientific publications" cited in the applicants' letter and that the PMRA's "review did not identify cause for concern that would have prevented the renewals of the products."[14] It is not clear from the PMRA's letter when the

[10] The PMRA must initiate periodic cyclical reviews of registered pest control products every 15 years and must also initiate reviews when new science could change the risk assessment: *PCPA*, s. 16; Olivastri Affidavit at para. 5, MR Tab 3, p. 574; Ireland Affidavit, Exhibit D (CTR Doc 2: RVD2017-01, Re-evaluation Decision of Glyphosate dated April 28, 2017 at p. 1), MR Tab 2, p. 370.
[11] Ireland Affidavit, Exhibit D (CTR Doc 2: RVD2017-01, Re-evaluation Decision of Glyphosate dated April 28, 2017), MR Tab 2, p. 365. See also Olivastri Affidavit at para 6, MR Tab 3, p. 574.
[12] Ireland Affidavit, Exhibit A (Letter dated October 27, 2022 from L. Bowman to F. Bissonnette), MR Tab 2, p. 13-25; Olivastri Affidavit at paras 9, 13-14, 17, 21, 25, MR Tab 3, pp. 575-580.
[13] Olivastri Affidavit at para 9 and Exhibits B1-B61, MR Tab 3, pp. 575, 600-1551.
[14] Ireland Affidavit, Exhibit C (Letter dated February 23, 2023 from F. Bissonnette to L. Bowman), MR Tab 2, p. 30.

PMRA became aware of the scientific publications or the nature, scope, process or timing of the PMRA's review of these publications.[15]

The R. 317 Request for the Certified Tribunal Record

10. In their Notice of Application, the applicants requested a copy of the certified record pursuant to Rule 317. This request was for:

> (a) The renewal application for the Product under submission number 2022-3929.
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> (b) All briefing notes prepared for PMRA decision makers and all decision documents prepared by PMRA decision [makers] about application/submission number 2022-3929.
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> (c) All renewal team or science team monographs, memoranda, and emails, prepared in respect of the decision to grant application/submission number 2022-3929, including documents regarding the applicants['] October 27, 2022 letter.
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> (d) Formal and informal policy decisions relied on by the PMRA in making decisions about the renewal.[16] [emphasis added]

11. Only items (b) and (c) are in dispute on this motion.

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[15] Olivastri Affidavit at paras 10-12, MR Tab 3, pp. 575-576.
[16] Notice of Application at para 40, MR Tab 5, pp. 2025-2026.

12. The PMRA did not object to the request and produced a certified record on February 23, 2023, containing 14 documents.[17] Among the documents are three PMRA memoranda concluding that the information provided by the applicants in their October 2022 letter did not change the PMRA's risk assessment of glyphosate.[18] However, no reasons are given for the stated conclusions, and the reviews themselves are not in the record.

13. Following receipt of the certified record, the applicants requested that the PMRA produce "all PMRA review memoranda and monographs from scientific staff at the Environmental Assessment Division (EAD) and the Health Evaluation Directorate (HED) of the PMRA that document when the PMRA became aware of the information cited in the October 27, 2022 letter and what specific reviews, analyses and conclusions the PMRA conducted in respect of each article." The applicants provided the PMRA with examples of the documents that are typically produced by the PMRA when it reviews new scientific information and requested that this documentation be produced if it exists, or alternatively that the PMRA confirm that no such documentation exists with respect to the Product's renewal.[19]

14. In response, the PMRA confirmed that it "does not have any additional review memoranda or monographs that were considered by the decision maker". However, the PMRA noted that "its scientists within EAD and HED continuously monitor published

[17] Ireland Affidavit, Exhibit D (Certified Tribunal Record), MR Tab 2, p. 34.
[18] Ireland Affidavit, Exhibit D (CTR Doc 7: Memo dated December 2022; CTR Doc 8: Memo dated December 7, 2022; CTR Doc 9: Memo dated December 7, 2022), MR Tab 2, pp. 493, 495, 497.
[19] Ireland Affidavit, Exhibit E (Letter dated March 2, 2023 from L. Bowman to A. Bourke), MR Tab 2, pp. 507-508. Exhibit E includes several PMRA documents, including review memoranda from scientific staff and a science management committee briefing note.

scientific literature and the publication of reviews by other regulators for new information that may be relevant to the risk assessment of pesticides."[20]

15. In response to a further request for the documents from the applicants,[21] counsel to the PMRA identified one individual within the PMRA, the Section Head of the Information Management Section who electronically signed the Product's registration certificate, as the "decision maker" and "confirm[ed] that all information that was considered by Ms. Beckman in respect of submission 2022-3929 was included in the CTR".[22]

PART II – ISSUES

16. Should the requested documents be produced by the PMRA pursuant to Rules 317 and 318 because they are relevant to the application, are in the possession of the PMRA and were before the PMRA when it made its decision to renew the Product's registration?

PART III – SUBMISSIONS

17. The applicants are entitled to the material in their Rule 317 request because the material is highly relevant to the application, is in the possession of the PMRA, and was before the PMRA when it made its decision to renew the Product's registration. If the PMRA is permitted to withhold this material, its decision may be immunized from review by this Court. The applicants would be prejudiced because the current record is unclear about the nature, extent, methods, and genuineness of the PMRA's review of the up-to-date science and the reasons for its conclusions. The current state of the record invites

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[20] Ireland Affidavit, Exhibit F (Letter dated March 13, 2023 from A. Bourke to L. Bowman), MR Tab 2, pp. 560-561.
[21] Ireland Affidavit, Exhibit G (Letter dated March 23, 2023 from L. Bowman to A. Bourke), MR Tab 2, pp. 563-564.
[22] Ireland Affidavit, Exhibit I (Letter dated March 31, 2023 from K. Lovell to L. Bowman), MR Tab 2, p. 569.

controversy about whether and how the PMRA assessed the risks from the scientific material in the October 2022 letter.

A. Rule 317 entitles the requester to material that is relevant to the application, is in the possession of the decision maker, and was before the decision maker when it made the decision under review

18. Rule 317 entitles a party to request material relevant to an application that is in the possession of a tribunal whose order is the subject of the application and not in the possession of the party.[23] The Federal Court of Appeal has explained that this rule entitles the requesting party to receive everything that was before the decision maker at the time it made its decision and that the applicant does not have in its possession.[24] This allows parties to effectively pursue their rights to challenge administrative decisions from a reasonableness perspective and have the reviewing court consider the evidence presented to the tribunal in question.[25]

19. The evidentiary record on a judicial review plays a fundamental role in ensuring that courts can conduct a meaningful review of administrative decision-makers: "If the reviewing court does not have evidence of what the administrative decision maker has relied upon, the reviewing court may not be able to detect a reviewable error. In other words, an inadequate evidentiary record before the reviewing court can immunize the

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[23] *Federal Courts Rules*, SOR/98-106, r. 317.
[24] *Canadian Copyright Licensing Agency (Access Copyright), v. Alberta*, 2015 FCA 268 at para 13 [***Access Copyright***]; *Canadian National Railway Company v. Canada (Transportation Agency)*, 2019 FCA 257 at para 12 [***Canadian National Railway***].
[25] *Access Copyright*, *ibid* at para 13.

decision maker from review."[26] For this reason, when there is any doubt or uncertainty as to the necessity of the documents, the scales weigh in favour of inclusion.[27]

20. Where the decision maker has not provided formal reasons for a decision, the evidentiary record plays a key role in the reviewing court's discernment of the decision maker's reasons.[28] The reviewing court must be able to discern the interpretation adopted by the decision maker from the record and determine whether that interpretation is reasonable.[29]

21. For material to be producible under Rules 317/318, the material must be actually relevant, as defined by the grounds of review in the notice of application; it must be in the possession of the administrative decision-maker, not others (e.g., another government entity); and it must have been before the administrative decision-maker when it made the decision under review.[30] Rule 317 does not serve the same purpose as documentary discovery and cannot be used on a fishing expedition.[31] Relevant factors include the precision of the request under Rule 317 and the existence of evidence that the requested material exists.[32] However, the overarching consideration is always whether disclosure would facilitate meaningful review.[33]

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[26] *Access Copyright*, *ibid* at para 14. See also *Tsleil-Waututh Nation v. Canada (Attorney General)*, 2017 FCA 128 at para 67 [***Tsleil-Waututh Nation***]; *GCT Canada Limited Partnership v. Canada (AG)*, 2021 FC 624 at para 24 [***GCT Canada***].
[27] *Canadian National Railway*, *supra* note 24 at para 14.
[28] *Tsleil-Waututh Nation*, *supra* note 26 at paras 68, 70-79.
[29] *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65 at para 123 [***Vavilov***]; *Safe Food Matters Inc. v. Canada (Attorney General)*, 2022 FCA 19 at para 41 [***Safe Food Matters***].
[30] *Tsleil-Waututh Nation*, *supra* note 26 at paras 107-114; *GCT Canada*, *supra* note 26 at para 23.
[31] *Tsleil-Waututh Nation*, *ibid* at paras 108, 115; *GCT Canada*, *ibid* at para 23.
[32] *Access Information Agency Inc v. Canada (Attorney General)*, 2007 FCA 224 at para 21; *Canadian Constitution Foundation v. Canada (Attorney General)*, 2022 FC 1233 at para 65.
[33] *GCT Canada*, *supra* note 26 at paras 24-26.

B. The material requested is highly relevant to the application

22. The requested material is highly relevant to the application. The application challenges the reasonableness of the PMRA's decision to renew the Product's registration. The Act requires that the PMRA conclude that the risks of the product are acceptable, which is defined as reasonable certainty that no harm will occur from use of or exposure to the product.[34] In the absence of such a conclusion, the PMRA cannot renew the product. The Act further requires the PMRA to perform a scientifically based assessment of risks to human health and the environment.[35]

23. The application alleges that the Minister did not engage in a scientifically based review of the risks of the Product before renewing its registration, as required by the Act. The Minister therefore renewed the registration for the Product without having reasonable certainty that no harm will occur to human health and the environment.[36]

24. The extent to which the PMRA considered and assessed the up-to-date science included in the October 2022 letter (or not), whether the PMRA used a scientifically based approach to that review, and whether the PMRA reached the required conclusion that there was reasonable certainty that no harm would occur to human health or the environment based on that review is central to the reasonableness of the decision in question.

25. Notably, the certified record includes three memoranda from PMRA scientific evaluators in the re-evaluation sections of the Health Evaluation Directorate (HED) and the Environmental Assessment Directorate (EAD) to the PMRA Renewal Coordinator.

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[34] *PCPA*, ss. 2(2), 7, 8.
[35] *PCPA*, s. 7(7)(a).
[36] Notice of Application at paras 3-5, 34-36, MR Tab 5, pp. 2018, 2024-2025.

These memoranda provide conclusions on acceptable risk, but do not disclose the process by which that conclusion was reached. Each memorandum "confirms" that "the information provided" in the applicants' October 2022 letter "does not change the current assessment on file that the risks [of glyphosate] are acceptable". The memoranda note that "Health Canada's PMRA has been monitoring the significant recent and ongoing scientific research and publications on glyphosate and continues to monitor for any new credible scientific information that becomes available in the scientific literature. Therefore, as part of this surveillance and monitoring of scientific literature, PMRA is aware of the scientific publications cited in the letter."[37] There is no explanation in these memoranda or elsewhere in the certified record as to the nature or extent of the PMRA's awareness or review of the referenced scientific publications or why the PMRA did not consider these new publications to change the conclusion of its 2017 risk assessment.

26. The production of memoranda assessing each publication and monographs weighing the evidence from each publication is necessary to understand the scientific analyses supporting the conclusion that there was scientifically based reasonable certainty that no harm would occur from renewal of the Product's registration. These analyses are key to answering important questions about whether the PMRA adhered to legal constraints in the Act and Regulations and/or reasonably interpreted the relevant provisions of the Act and Regulations,[38] including but not limited to:

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[37] Ireland Affidavit, Exhibit D (CTR Doc 7: Memo dated December 2022; CTR Doc 8 :Memo dated December 7, 2022; CTR Doc 9: Memo dated December 7, 2022), MR Tab 2, pp. 493, 495, 497.
[38] *PCPA*, ss. 2(2), 4(1), 7, 8; Regulations, ss. 6, 8, 16.

(a) Did the PMRA reasonably interpret "environmental risk" to include non-toxicological risks to forests, freshwater systems and pollinator habitat? Or were these risks simply ignored?[39]

(b) Was the PMRA's consideration of the applicants' evidence on the risks to the human microbiome and the decision to give that evidence less weight than other evidence about the microbiome transparent and intelligible in the sense that it was "scientifically based" and followed the PMRA's own risk assessment and weight of evidence policies?[40]

(c) Did the PMRA consider new evidence on neurological and cancer risks?

(d) Did the PMRA update the risk assessment by evaluating the information in the letter to reach updated, scientifically based conclusions on acceptable risk or was the letter simply skimmed and the renewal treated as administrative?[41]

[39] Olivastri Affidavit at paras 13-16, MR Tab 3, pp. 576-577.
[40] Olivastri Affidavit at paras 17-21, MR Tab 3, pp. 577-579; see also Exhibit F (PMRA Framework for Risk Assessment and Risk Management of Pest Control Products), MR Tab 3, p. 1565 and Exhibit N (PMRA Weight of Evidence document), MR Tab 3, p. 1650.
[41] Olivastri Affidavit at paras 28-33 and 38-49, MR Tab 3, pp. 580-582, 583-587.

C. The applicants have provided evidence that the material likely exists, is in the possession of the PMRA and was before the PMRA when it made the renewal decision

27. The applicants have an evidentiary basis to believe that the requested documents exist. The applicants have previously been involved in multiple judicial reviews involving the PMRA and have seen multiple certified records emanating from the PMRA.[42]

28. The PMRA has a defined process for conducting a scientifically based review and updating its risk assessment. The PMRA structures its reviews through two divisions: the Health Evaluation Division (HED) and the Environmental Assessment Division (EAD). Each division reviews individual scientific sources and documents those reviews through memoranda or data evaluation reports.[43] To compile an updated risk assessment, those individual memoranda are summarized in a monograph that is then peer-reviewed.[44]

29. This monograph compiles assessment conclusions and documents the weighing of the various sources of evidence. Health Canada's weight of evidence policy, which the PMRA says it follows, also sets out a process for documenting how the risk assessment is

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[42] See e.g. the Affidavit of Mary Lou McDonald, affirmed May 3, 2023 [**McDonald Affidavit**] at paras 6, 9-10, MR Tab 4, p. 1700-1701; Olivastri Affidavit at para 47, MR Tab 3, p. 586; *Équiterre v. Canada (Health)*, 2016 FC 554; *David Suzuki Foundation v. Canada (Attorney General)*, 2019 FC 411; *Safe Food Matters*, *supra* note 29; *Safe Food Matters Inc. v. Canada (Attorney General)*, 2022 FC 915.

[43] McDonald Affidavit, Exhibit D (CTR Doc 42 in T-277-19), MR Tab 4, p.1956; Olivastri Affidavit, Exhibit O (Affidavit of Scott Kirby) at paras 19-20, MR Tab 3, p .1682; Ireland Affidavit, Exhibit E (Letter dated March 2, 2023 from L. Bowman to A. Bourke and 1st, 2nd, 4th, 5th and 6th attachments to letter), MR Tab 2, pp. 507-508, 509, 513, 528, 531, 534.

[44] See e.g. the 2015 toxicology monograph produced in the McDonald Affidavit, Exhibit D (CTR Doc 40 in T-277-19), MR Tab 4, p. 1808. See also the description of a similar process involving compiling a peer-reviewed monograph used by the Environmental Assessment Division in the Affidavit of Scott Kirby included in the Olivastri Affidavit, Exhibit O at paras 19-26, MR Tab 3, pp. 1682-1684.

conducted and the rationale for either including or excluding certain sources of evidence as well as the rationale for the weight given to each source.[45]

30. Finally, after the scientific evaluators have completed their work and produced an updated and peer-reviewed weight of evidence analysis, the material is sent to senior managers for final approval.[46] Discussions around such approvals are documented in the science management committee, directors general or other briefing notes, minutes and agendas.[47] Accordingly, the determination of acceptable risk is a collaborative process involving multiple scientific reviewers, peer review and oversight by committees of scientists and managers within the PMRA. Although the Minister is formally the decision-maker under the Act, the Minister has no actual role in the decision.

31. The applicants' Rule 317 request was sufficiently specific to encompass any materials relied on by the PMRA in reaching the conclusion that the risks of the Product remained acceptable, including substantive PMRA reviews or analyses of any of the articles cited in the letter and any documents comprising the rationale underlying the PMRA's conclusion on acceptability of risks. The Rule 317 request sets out the specific categories of documents that are relevant to the PMRA's scientific review process.[48]

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[45] Olivastri Affidavit at paras 45-46 and Exhibit N (PMRA Weight of Evidence document), MR Tab 3, pp. 585-586, 1650.
[46] Olivastri Affidavit, Exhibit O (Affidavit of Scott Kirby at paras 25-26), MR Tab 3, p. 1684.
[47] Ireland Affidavit, Exhibit E (Letter dated March 2, 2023 from L. Bowman to A. Bourke and 3rd attachment to letter), MR Tab 2, pp. 507-508, 517; McDonald Affidavit, Exhibit D (CTR Docs 16-28, 44-47 in T-277-19), MR Tab 4, pp.1755-1807, 1967-2015. Notably, the decision in issue in that case was held to be unreasonable due to a failure to address the requirements in the Act by the Federal Court of Appeal in *Safe Food Matters*, *supra* note 29.
[48] Notice of Application at para 40, MR Tab 5, pp. 2025-2026.

32. There is also evidence indicating that in the case of renewals, the PMRA does not typically update its risk assessment. The PMRA treats renewals as "category D" decisions without data requirements.[49] The current certified record is ambiguous regarding whether the PMRA treated the renewal as administrative (which is the standard PMRA procedure and which the applicants say would violate the requirements in the Act and Regulations) or whether the PMRA updated the risk assessment in accordance with the requirements in the Act and Regulations. Since this distinction lies at the heart of the judicial review, a complete record is necessary to provide the PMRA's full analysis.

D. The PMRA insinuates that further analysis exists but is not producible based on a narrow conception of who the "decision-maker" is

33. In correspondence concerning the Rule 317 request, counsel for the PMRA have not denied that further material evidencing the rationale for the PMRA's scientific conclusions exists. Rather, they have suggested that they do not have to produce the material evidencing the PMRA's reviews of the new science on glyphosate risks, solely because they consider the individual within the PMRA who electronically signed the registration certificate (the Section Head of the Information Management Section) to be the "decision maker" and these reviews were not before this individual when she signed the renewal certificate.[50]

34. The PMRA seeks to have it both ways by emphasizing the administrative nature of the decision in narrowly defining who the "decision-maker" is but appears to be also taking the position that the decision-maker relied on the substantive conclusions of scientific

[49] Olivastri Affidavit at paras 29-31, Exhibits G and H, MR Tab 3, pp. 580-581, 1591, 1598.
[50] Ireland Affidavit, Exhibit I (Letter dated March 31, 2023 from K. Lovell to L. Bowman), MR Tab 2, p. 569; Ireland Affidavit, Exhibit F (Letter dated March 13, 2023 from A. Bourke to L. Bowman), MR Tab 2, p. 560.

evaluators in the certified record. If the PMRA relies on an updated scientific evaluation to defend the reasonableness of the decision, then that evaluation must be fully disclosed to ensure it complies with the Act.

35. The "decision" under the statute is a scientific conclusion, not an administrative one. The decision at issue is a decision that the Product's registration could be renewed because, under ss. 2(2), 7 and 8 of the Act, the health and environmental risks are acceptable for another five-year term of registration. The assessment of acceptable risk must be "scientifically based" under s. 7(7) of the Act. The "decision" was therefore made by the teams at the PMRA who conducted the scientific assessment of acceptable risk.

36. The Respondents seek to bifurcate the decision-making process at the PMRA by establishing that a person who had no knowledge and conducted no assessment of acceptable risk is the "decision-maker" because that individual signed the decision document. The respondents seek to shield the PMRA's assessment of new science on the risks of glyphosate, or lack thereof, from the scrutiny of this Court. The information relevant to a PMRA decision regarding the acceptability of health and environmental risks of a pest control product is the scientific analyses supporting the conclusion that there was scientifically based reasonable certainty that no harm would occur.

E. The applicants will be prejudiced, and meaningful review frustrated if the material is not produced

37. The production of the requested material, and clarification of the nature of the PMRA's review, is necessary for the Court to review the decision challenged in the application. The certified record in its current form is prejudicial to the applicants and unhelpful for the Court: the record contains documents that make vague assertions that

some review or analysis of the concerns and evidence raised in the applicants' October 2022 letter took place prior to the decision to renew the Product's registration. However, no documentation of the process followed or the scientific rationale for the conclusion on acceptable risk has been produced.

38. Without a record of the process by which the decision on acceptable risk was made or the rationale for the conclusion that the risks of the Product are acceptable, the Court cannot know if the requirements of the Act and Regulations were followed.[51] The Court would be asked to infer that a scientifically based review of acceptable risk, based on up-to-date scientific information, took place and that that review was relied on in making the decision to renew the Product's registration, without being able to assess the nature and reasonableness of that review in relation to the specific requirements in the Act.

39. If the PMRA is not required to produce the underlying analysis for its conclusion that, in light of the new science since 2017 on the risks of glyphosate, the risks of the Product are acceptable, its decision to renew the Product's registration would be immunized from meaningful review by this Court. The applicants would also be severely prejudiced because the PMRA can invite inferences about the nature of its review, and whether that review complied with relevant statutory provisions, without disclosing records central to that review to the applicants or the Court.

[51] *Vavilov*, *supra* note 29 at paras 123, 137; *Safe Food Matters*, *supra* note 29 at paras 58, 62, 65.

PART IV – ORDER SOUGHT

40. The applicants request:

(a) An order under Rule 318 that the respondent Attorney General of Canada within 20 days produce all relevant documents in accordance with the applicants' Rule 317 request;

(b) Such other relief as this Court may find appropriate; and

(c) An order that each party shall bear their own costs.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

Dated at Toronto this 8th day of May, 2023.

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PART V – LIST OF AUTHORITIES

Legislation

1. Federal Courts Rules, SOR/98-106
2. Pest Control Products Act, SC 2002, c. 28
3. Pest Control Products Regulations, SOR/206-124

Jurisprudence

1. *Access Information Agency Inc v. Canada (Attorney General)*, 2007 FCA 224
2. *Canadian Copyright Licensing Agency (Access Copyright), v. Alberta*, 2015 FCA 268
3. *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65
4. *Canadian Constitution Foundation v. Canada (Attorney General)*, 2022 FC 1233
5. *Canadian National Railway Company v. Canada (Transportation Agency)*, 2019 FCA 257
6. *David Suzuki Foundation v. Canada (Attorney General)*, 2019 FC 411
7. *Équiterre v. Canada (Health)*, 2016 FC 554
8. *GCT Canada Limited Partnership v. Canada (Attorney General)*, 2021 FC 624
9. *Safe Food Matters Inc. v. Canada (Attorney General)*, 2022 FC 915
10. *Safe Food Matters Inc. v. Canada (Attorney General)*, 2022 FCA 19
11. *Tsleil-Waututh Nation v. Canada (Attorney General)*, 2017 FCA 128

APPENDIX "A" – RELEVANT STATUTES AND REGULATIONS

Federal Courts Rules, SOR/98-106
Règles des Cours fédérales, DORS 98-106

Material from tribunal

317 (1) A party may request material relevant to an application that is in the possession of a tribunal whose order is the subject of the application and not in the possession of the party by serving on the tribunal and filing a written request, identifying the material requested.

Matériel en la possession de l'office fédéral

317 (1) Toute partie peut demander la transmission des documents ou des éléments matériels pertinents quant à la demande, qu'elle n'a pas mais qui sont en la possession de l'office fédéral dont l'ordonnance fait l'objet de la demande, en signifiant à l'office une requête à cet effet puis en la déposant. La requête précise les documents ou les éléments matériels demandés.

Request in notice of application

(2) An applicant may include a request under subsection (1) in its notice of application.

Demande inclue dans l'avis de demande

(2) Un demandeur peut inclure sa demande de transmission de documents dans son avis de demande.

Service of request

(3) If an applicant does not include a request under subsection (1) in its notice of application, the applicant shall serve the request on the other parties.

Signification de la demande de transmission

(3) Si le demandeur n'inclut pas sa demande de transmission de documents dans son avis de demande, il est tenu de signifier cette demande aux autres parties.

Material to be transmitted

318 (1) Within 20 days after service of a request under rule 317, the tribunal shall transmit

(a) a certified copy of the requested material to the Registry and to the party making the request; or

Documents à transmettre

318 (1) Dans les 20 jours suivant la signification de la demande de transmission visée à la règle 317, l'office fédéral transmet :

a) au greffe et à la partie qui en a fait la demande une copie certifiée conforme des documents en cause;

(b) where the material cannot be reproduced, the original material to the Registry.

Objection by tribunal

(2) Where a tribunal or party objects to a request under rule 317, the tribunal or the party shall inform all parties and the Administrator, in writing, of the reasons for the objection.

Directions as to procedure

(3) The Court may give directions to the parties and to a tribunal as to the procedure for making submissions with respect to an objection under subsection (2).

Order

(4) The Court may, after hearing submissions with respect to an objection under subsection (2), order that a certified copy, or the original, of all or part of the material requested be forwarded to the Registry.

…

Notice of motion

359 Except with leave of the Court, a motion shall be initiated by a notice of motion, in Form 359, setting out

(a) in respect of a motion other than one brought under rule 369 or 369.2, the time, place and estimated duration of the hearing of the motion;

(b) the relief sought;

(c) the grounds intended to be argued, including a reference to any

b) au greffe les documents qui ne se prêtent pas à la reproduction et les éléments matériels en cause.

Opposition de l'office fédéral

(2) Si l'office fédéral ou une partie s'opposent à la demande de transmission, ils informent par écrit toutes les parties et l'administrateur des motifs de leur opposition.

Directives de la Cour

(3) La Cour peut donner aux parties et à l'office fédéral des directives sur la façon de procéder pour présenter des observations au sujet d'une opposition à la demande de transmission.

Ordonnance

(4) La Cour peut, après avoir entendu les observations sur l'opposition, ordonner qu'une copie certifiée conforme ou l'original des documents ou que les éléments matériels soient transmis, en totalité ou en partie, au greffe.

…

Avis de requête

359 Sauf avec l'autorisation de la Cour, toute requête est présentée au moyen d'un avis de requête établi selon la formule 359 et précise :

a) sauf s'il s'agit d'une requête présentée selon la règle 369 ou 369.2, la date, l'heure, le lieu et la durée prévue de l'audition de la requête;

b) la réparation recherchée;

statutory provision or rule to be relied on; and

(d) a list of the documents or other material to be used for the purposes of the motion.

…

Motions in writing

369 (1) A party may, in a notice of motion, request that the motion be decided on the basis of written representations.

Request for oral hearing

(2) A respondent to a motion brought in accordance with subsection (1) shall serve and file a respondent's record within 10 days after being served under rule 364 and, if the respondent objects to disposition of the motion in writing, indicate in its written representations or memorandum of fact and law the reasons why the motion should not be disposed of in writing.

Reply

(3) A moving party may serve and file written representations in reply within four days after being served with a respondent's record under subsection (2).

Disposition of motion

(4) On the filing of a reply under subsection (3) or on the expiration of the period allowed for a reply, the Court may dispose of a motion in writing or

c) les motifs qui seront invoqués, avec mention de toute disposition législative ou règle applicable;

d) la liste des documents et éléments matériels qui seront utilisés dans le cadre de la requête.

…

Procédure de requête écrite

369 (1) Le requérant peut, dans l'avis de requête, demander que la décision à l'égard de la requête soit prise uniquement sur la base de ses prétentions écrites.

Demande d'audience

(2) L'intimé signifie et dépose son dossier de réponse dans les 10 jours suivant la signification visée à la règle 364 et, s'il demande l'audition de la requête, inclut une mention à cet effet, accompagnée des raisons justifiant l'audition, dans ses prétentions écrites ou son mémoire des faits et du droit.

Réponse du requérant

(3) Le requérant peut signifier et déposer des prétentions écrites en réponse au dossier de réponse dans les quatre jours après en avoir reçu signification.

Décision

(4) Dès le dépôt de la réponse visée au paragraphe (3) ou dès l'expiration du délai prévu à cette fin, la Cour peut statuer sur la requête par écrit ou fixer les date, heure et lieu de l'audition de la requête.

fix a time and place for an oral hearing of the motion.

…

Discretionary powers of Court

400 (1) The Court shall have full discretionary power over the amount and allocation of costs and the determination of by whom they are to be paid.

Crown

(2) Costs may be awarded to or against the Crown.

Factors in awarding costs

(3) In exercising its discretion under subsection (1), the Court may consider

(a) the result of the proceeding;

(b) the amounts claimed and the amounts recovered;

(c) the importance and complexity of the issues;

(d) the apportionment of liability;

(e) any written offer to settle;

(f) any offer to contribute made under rule 421;

(g) the amount of work;

(h) whether the public interest in having the proceeding litigated justifies a particular award of costs;

(i) any conduct of a party that tended to shorten or unnecessarily lengthen the duration of the proceeding;

…

Pouvoir discrétionnaire de la Cour

400 (1) La Cour a le pouvoir discrétionnaire de déterminer le montant des dépens, de les répartir et de désigner les personnes qui doivent les payer.

La Couronne

(2) Les dépens peuvent être adjugés à la Couronne ou contre elle.

Facteurs à prendre en compte

(3) Dans l'exercice de son pouvoir discrétionnaire en application du paragraphe (1), la Cour peut tenir compte de l'un ou l'autre des facteurs suivants :

a) le résultat de l'instance;

b) les sommes réclamées et les sommes recouvrées;

c) l'importance et la complexité des questions en litige;

d) le partage de la responsabilité;

e) toute offre écrite de règlement;

f) toute offre de contribution faite en vertu de la règle 421;

g) la charge de travail;

h) le fait que l'intérêt public dans la résolution judiciaire de l'instance justifie une adjudication particulière des dépens;

(j) the failure by a party to admit anything that should have been admitted or to serve a request to admit;

(k) whether any step in the proceeding was

(i) improper, vexatious or unnecessary, or

(ii) taken through negligence, mistake or excessive caution;

(l) whether more than one set of costs should be allowed, where two or more parties were represented by different solicitors or were represented by the same solicitor but separated their defence unnecessarily;

(m) whether two or more parties, represented by the same solicitor, initiated separate proceedings unnecessarily;

(n) whether a party who was successful in an action exaggerated a claim, including a counterclaim or third party claim, to avoid the operation of rules 292 to 299;

(n.1) whether the expense required to have an expert witness give evidence was justified given

(i) the nature of the litigation, its public significance and any need to clarify the law,

(ii) the number, complexity or technical nature of the issues in dispute, or

i) la conduite d'une partie qui a eu pour effet d'abréger ou de prolonger inutilement la durée de l'instance;

j) le défaut de la part d'une partie de signifier une demande visée à la règle 255 ou de reconnaître ce qui aurait dû être admis;

k) la question de savoir si une mesure prise au cours de l'instance, selon le cas :

(i) était inappropriée, vexatoire ou inutile,

(ii) a été entreprise de manière négligente, par erreur ou avec trop de circonspection;

l) la question de savoir si plus d'un mémoire de dépens devrait être accordé lorsque deux ou plusieurs parties sont représentées par différents avocats ou lorsque, étant représentées par le même avocat, elles ont scindé inutilement leur défense;

m) la question de savoir si deux ou plusieurs parties représentées par le même avocat ont engagé inutilement des instances distinctes;

n) la question de savoir si la partie qui a eu gain de cause dans une action a exagéré le montant de sa réclamation, notamment celle indiquée dans la demande reconventionnelle ou la mise en cause, pour éviter l'application des règles 292 à 299;

n.1) la question de savoir si les dépenses engagées pour la déposition d'un témoin expert étaient justifiées

(iii) the amount in dispute in the proceeding; and

(o) any other matter that it considers relevant.

compte tenu de l'un ou l'autre des facteurs suivants :

(i) la nature du litige, son importance pour le public et la nécessité de clarifier le droit,

(ii) le nombre, la complexité ou la nature technique des questions en litige,

(iii) la somme en litige;

o) toute autre question qu'elle juge pertinente.

Tariff B

(4) The Court may fix all or part of any costs by reference to Tariff B and may award a lump sum in lieu of, or in addition to, any assessed costs.

Tarif B

(4) La Cour peut fixer tout ou partie des dépens en se reportant au tarif B et adjuger une somme globale au lieu ou en sus des dépens taxés.

Directions re assessment

(5) Where the Court orders that costs be assessed in accordance with Tariff B, the Court may direct that the assessment be performed under a specific column or combination of columns of the table to that Tariff.

Directives de la Cour

(5) Dans le cas où la Cour ordonne que les dépens soient taxés conformément au tarif B, elle peut donner des directives prescrivant que la taxation soit faite selon une colonne déterminée ou une combinaison de colonnes du tableau de ce tarif.

Further discretion of Court

(6) Notwithstanding any other provision of these Rules, the Court may

(a) award or refuse costs in respect of a particular issue or step in a proceeding;

(b) award assessed costs or a percentage of assessed costs up to

Autres pouvoirs discrétionnaires de la Cour

(6) Malgré toute autre disposition des présentes règles, la Cour peut :

a) adjuger ou refuser d'adjuger les dépens à l'égard d'une question litigieuse ou d'une procédure particulières;

and including a specified step in a proceeding;

(c) award all or part of costs on a solicitor-and-client basis; or

(d) award costs against a successful party.

Award and payment of costs

(7) Costs shall be awarded to the party who is entitled to receive the costs and not to the party's solicitor, but they may be paid to the party's solicitor in trust.

b) adjuger l'ensemble ou un pourcentage des dépens taxés, jusqu'à une étape précise de l'instance;

c) adjuger tout ou partie des dépens sur une base avocat-client;

d) condamner aux dépens la partie qui obtient gain de cause.

Adjudication et paiement des dépens

(7) Les dépens sont adjugés à la partie qui y a droit et non à son avocat, mais ils peuvent être payés en fiducie à celui-ci.

***Pest Control Products Act*, SC 2002, c 28**
***Loi sur les produits antiparasitaires*, LC 2002, c 28**

Interpretation

Définitions et interpretation

Definitions

Définitions

2 (1) The definitions in this subsection apply in this Act.

2 (1) Les définitions qui suivent s'appliquent à la présente loi.

…

…

Acceptable risks

Risques acceptables

(2) For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

(2) Pour l'application de la présente loi, les risques sanitaires ou environnementaux d'un produit antiparasitaire sont acceptables s'il existe une certitude raisonnable qu'aucun dommage à la santé humaine, aux générations futures ou à l'environnement ne résultera de l'exposition au produit ou de l'utilisation de celui-ci, compte tenu des conditions d'homologation proposées ou fixées.

…

…

Mandate

Mission

Primary objective

Objectif premier

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

4 (1) Pour l'application de la présente loi, le ministre a comme objectif premier de prévenir les risques inacceptables pour les individus et l'environnement que présente l'utilisation des produits antiparasitaires.

Ancillary objectives

Objectifs connexes

(2) Consistent with, and in furtherance of, the primary objective, the Minister shall

(2) À cet égard, le ministre doit :

(a) support sustainable development designed to enable the needs of the present to be met without

a) promouvoir le développement durable, soit un développement qui permet de répondre aux besoins du présent sans compromettre la

compromising the ability of future generations to meet their own needs;

(b) seek to minimize health and environmental risks posed by pest control products and encourage the development and implementation of innovative, sustainable pest management strategies by facilitating access to pest control products that pose lower risks and by other appropriate measures;

(c) encourage public awareness in relation to pest control products by informing the public, facilitating public access to relevant information and public participation in the decision-making process; and

(d) ensure that only those pest control products that are determined to be of acceptable value are approved for use in Canada.

possibilité pour les générations futures de satisfaire les leurs;

b) tenter de réduire au minimum les risques sanitaires et environnementaux que présentent les produits antiparasitaires et d'encourager le développement et la mise en oeuvre de stratégies de lutte antiparasitaire durables et innovatrices — en facilitant l'accès à des produits antiparasitaires à risque réduit — et d'autres mesures indiquées;

c) sensibiliser le public aux produits antiparasitaires en l'informant, en favorisant son accès aux renseignements pertinents et en encourageant sa participation au processus de prise de décision;

d) veiller à ce que seuls les produits antiparasitaires dont la valeur a été déterminée comme acceptable soient approuvés pour utilisation au Canada.

…

Application to Minister

7 (1) An application to register a pest control product or to amend the product's registration must be made to the Minister in the form and manner directed by the Minister and must include any information or other thing that is required by the regulations to accompany the application.

Use of information provided by registrants

(2) If the Minister determines that the active ingredient of the applicant's pest

…

Demande au ministre

7 (1) Les demandes d'homologation ou de modification d'homologation d'un produit antiparasitaire sont présentées au ministre, selon les modalités qu'il précise, et doivent être accompagnées des renseignements et autres éléments prévus par règlement.

Utilisation des renseignements fournis par des titulaires

(2) S'il conclut que le principe actif du produit antiparasitaire du demandeur est équivalent au principe actif d'un produit

control product is equivalent to the active ingredient of a registered pest control product, the Minister shall, subject to and in accordance with the regulations, permit the applicant to use or rely on any information referred to in subsection (1) that has been provided by any registrant if the Minister is satisfied that the information

(a) is relevant to the registered pest control product that contains the equivalent active ingredient; and

(b) is necessary to support the application.

Foreign review or evaluation

(2.1) For the purposes of subsection (1), the applicant may include information that is available from a review or evaluation of a pest control product conducted by the government of another member country of the Organisation for Economic Co-operation and Development if the proposed use of the pest control product in Canada would be under conditions similar to those under which the foreign review or evaluation was conducted.

Evaluation of pest control product

(3) If the Minister is satisfied that the application has been made in accordance with subsection (1), (2) or (2.1), the Minister shall

(a) in accordance with the regulations, if any, conduct any evaluations that the Minister considers necessary with respect to the health or environmental risks or

antiparasitaire homologué, le ministre permet au demandeur, sous réserve des règlements et en conformité avec ceux-ci, d'utiliser tout renseignement visé au paragraphe (1) fourni par un titulaire, ou de se fier à un tel renseignement, s'il est convaincu que ce renseignement :

a) d'une part, se rapporte au produit antiparasitaire homologué contenant le principe actif équivalent;

b) d'autre part, est nécessaire à l'appui de la demande.

Examen ou évaluation d'un pays étranger

(2.1) Pour l'application du paragraphe (1), le demandeur peut inclure des renseignements obtenus de l'examen ou de l'évaluation d'un produit antiparasitaire effectué par le gouvernement d'un autre pays membre de l'Organisation de coopération et de développement économiques, si les conditions de l'utilisation proposée du produit antiparasitaire au Canada sont semblables aux conditions dans lesquelles l'examen ou l'évaluation a été effectué dans cet autre pays.

Évaluation du produit

(3) Si le ministre est convaincu que la demande a été faite conformément aux paragraphes (1), (2) ou (2.1), il procède :

a) en conformité avec les éventuels règlements, aux évaluations qu'il juge nécessaires en ce qui concerne la valeur du produit ou les risques sanitaires ou environnementaux qu'il présente;

the value of the pest control product;

(b) expedite evaluations with respect to a pest control product that may reasonably be expected to pose lower health or environmental risks; and

(c) carry out any consultation required by section 28.

b) à l'exécution rapide des évaluations qui concernent un produit antiparasitaire dont il peut raisonnablement prévoir des risques sanitaires ou environnementaux réduits;

c) s'il y a lieu, aux consultations exigées par l'article 28.

Other information

(4) The Minister may, by delivering a notice in writing, request an applicant to provide the Minister with other information in support of the application within the time and in the form specified in the notice.

Renseignements supplémentaires

(4) Le ministre peut, dans un avis écrit, exiger du demandeur qu'il lui communique tout autre renseignement à l'appui de sa demande en la forme et dans le délai qu'il précise dans l'avis.

Denial of application

(5) The Minister shall deny an application if the applicant does not comply with a notice under subsection (4).

Refus de donner suite

(5) Le ministre rejette la demande si le demandeur ne se conforme pas à l'avis.

Burden of persuasion and consideration of information

(6) During an evaluation,

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

(b) the Minister shall consider the information provided by the applicant in support of the application and may consider additional information, but the Minister shall give the applicant a reasonable opportunity to make

Charge de la preuve et renseignements pris en compte

(6) Lors des évaluations :

a) il incombe au demandeur de convaincre le ministre que la valeur du produit et les risques sanitaires et environnementaux qu'il présente sont acceptables;

b) le ministre prend en compte tout renseignement fourni par le demandeur à l'appui de sa demande et peut prendre en compte tout autre renseignement à condition, dans ce cas, de donner au demandeur, avant

representations in respect of the additional information before completing the evaluation.

Scientific approach

(7) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall

(a) apply a scientifically based approach; and

(b) in relation to health risks, if a decision referred to in paragraph 28(1)(a) or (b) is being made or has been made in relation to a pest control product,

(i) among other relevant factors, consider available information on aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational sources, including drinking water and use in and around homes and schools, and cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity,

(ii) apply appropriate margins of safety to take into account, among other relevant factors, the use of animal experimentation data and the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors, and

la fin des évaluations, la possibilité de présenter ses observations.

Approche scientifique

(7) Lorsqu'il évalue les risques sanitaires et environnementaux d'un produit antiparasitaire et détermine s'ils sont acceptables, le ministre :

a) adopte une approche qui s'appuie sur une base scientifique;

b) à l'égard des risques sanitaires, dans le cas où une décision visée aux alinéas 28(1)a) ou b) est sur le point d'être prise ou a été prise relativement au produit antiparasitaire :

(i) prend notamment en considération les renseignements disponibles sur l'exposition globale au produit antiparasitaire, soit l'exposition alimentaire et l'exposition d'autres sources ne provenant pas du milieu de travail, notamment l'eau potable et l'utilisation du produit dans les maisons et les écoles et autour de celles-ci, ainsi que les effets cumulatifs du produit antiparasitaire et d'autres produits antiparasitaires ayant un mécanisme de toxicité commun,

(ii) applique des marges de sécurité appropriées pour prendre notamment en compte l'utilisation de données d'expérimentation sur les animaux et les différentes sensibilités aux produits antiparasitaires des principaux sous-groupes identifiables,

(iii) in the case of a threshold effect, if the product is proposed for use in or around homes or schools, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph (ii) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate.

notamment les femmes enceintes, les nourrissons, les enfants, les femmes et les personnes âgées,

(iii) dans le cas d'un effet de seuil et si le produit est destiné à une utilisation dans les maisons ou les écoles ou autour de celles-ci, applique une marge de sécurité supérieure de dix fois à celle qui serait autrement applicable en vertu du sous-alinéa (ii) relativement à cet effet de seuil pour tenir compte de la toxicité prénatale et postnatale potentielle et du degré de complétude des données d'exposition et de toxicité relatives aux nourrissons et aux enfants, à moins que, sur la base de données scientifiques fiables, il ait jugé qu'une marge de sécurité différente conviendrait mieux.

Government policy to be given effect in evaluation

(8) In evaluating the health and environmental risks and the value of a pest control product, the Minister shall give effect to government policy.

Politique gouvernementale

(8) Lorsqu'il évalue la valeur du produit antiparasitaire et les risques sanitaires et environnementaux qu'il présente, le ministre donne effet à la politique gouvernementale.

Comparative risk and value assessment

(9) In determining whether the health and environmental risks and the value of a pest control product are acceptable, the Minister may, in accordance with the regulations, if any, take into account information regarding the risks and value of other pest control products that are registered for the same use.

Évaluation comparative des risques et de la valeur

(9) Lorsqu'il détermine si la valeur d'un produit antiparasitaire et les risques sanitaires et environnementaux qu'il présente sont acceptables, le ministre peut, en conformité avec les éventuels règlements, prendre en compte les renseignements sur la valeur et les risques d'autres produits homologués pour la même utilisation.

Representations

(10) For the purposes of subsection (9), the Minister shall, before making the determination, give the applicant a reasonable opportunity to make representations in respect of the information referred to in that subsection.

Registration or amendment

8 (1) If the Minister considers that the health and environmental risks and the value of the pest control product are acceptable after any required evaluations and consultations have been completed, the Minister shall register the product or amend its registration in accordance with the regulations, if any, by

(a) specifying the conditions relating to its manufacture, handling, storage, transport, import, export, packaging, distribution, use or disposition, including conditions relating to its composition, and, subject to subsection (2), the conditions relating to its label;

(b) assigning a registration number to the product in the case of a new registration and, where the Minister considers it appropriate, in the case of an amendment; and

(c) specifying the period for which the registration or amended registration is valid, which period may be either finite or indefinite.

Observations

(10) Pour l'application du paragraphe (9) et avant de prendre une décision définitive, le ministre donne au demandeur la possibilité de présenter ses observations sur les renseignements visés à ce paragraphe.

Délivrance et modification de l'homologation

8 (1) Si, au terme des évaluations et des consultations requises, il conclut que la valeur du produit antiparasitaire ainsi que les risques sanitaires et environnementaux qu'il présente sont acceptables, le ministre homologue le produit ou apporte les modifications demandées, en conformité avec les éventuels règlements, et pour ce faire :

a) il détermine les conditions relatives à la fabrication, à la manipulation, au stockage, au transport, à l'importation, à l'exportation, à l'emballage, à la distribution, à l'utilisation ou à la disposition du produit, notamment celles relatives à sa composition, et, sous réserve du paragraphe (2), les conditions relatives à son étiquette;

b) il attribue au produit un numéro d'homologation, dans le cas d'une nouvelle homologation et, s'il le juge à propos, dans le cas d'une modification;

c) il fixe la période de validité — déterminée ou non — de l'homologation ou de l'homologation modifiée.

Conditions relating to label

(2) The Minister may specify conditions relating to the label of a pest control product, otherwise than in accordance with the regulations, if the Minister is satisfied that the purposes of this Act can be met by so doing.

Conditions concernant l'étiquette

(2) Le ministre peut spécifier des conditions concernant l'étiquette d'un produit antiparasitaire, autrement qu'en conformité avec les règlements, s'il est convaincu que les objectifs de la présente loi peuvent être remplis.

Provision of safety information to workplaces

(3) Without limiting the generality of paragraph (1)(a), the Minister shall specify, as a condition of registration, the requirement for product safety information, including a material safety data sheet for the product, to be provided to workplaces where the pest control product is used or manufactured, in accordance with the regulations made under paragraph 67(1)(s).

Renseignements sur la sécurité fournis aux lieux de travail

(3) Sans que soit limitée la portée générale de l'alinéa (1)a), le ministre fixe, comme condition d'homologation, la fourniture de renseignements sur la sécurité du produit antiparasitaire, notamment une fiche signalétique, aux lieux de travail où celui-ci est utilisé ou fabriqué, en conformité avec les règlements pris en vertu de l'alinéa 67(1)s).

Denial of application

(4) The Minister shall deny an application referred to in subsection 7(1) if the Minister does not consider that the health or environmental risks of a pest control product are, or its value is, acceptable.

Rejet de la demande

(4) Le ministre rejette la demande visée au paragraphe 7(1) s'il n'arrive pas aux conclusions visées au paragraphe (1).

Sales data

(5) A registrant of a pest control product shall, as a condition of registration, record, retain and report to the Minister information on sales of the product in the form and manner directed by the Minister and in accordance with the regulations made under paragraph 67(1)(u).

Données sur la vente

(5) Comme condition d'homologation, le titulaire d'un produit antiparasitaire établit et conserve un registre des renseignements concernant les ventes du produit et transmet au ministre un rapport sur ces renseignements, selon les modalités fixées par le ministre et en conformité avec les règlements pris en vertu de l'alinéa 67(1)u).

Former registrants

(6) The obligation under subsection (5) to retain and report sales information in respect of a pest control product continues to apply to a former registrant after that product ceases to be registered.

…

Minister's discretion to initiate re-evaluation

16 (1) The Minister may initiate the 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.

Minister required to initiate re-evaluation

(2) Without limiting the generality of subsection (1),

(a) if a decision of a type referred to in paragraph 28(1)(a) or (b) was made in relation to a pest control product on or after April 1, 1995, the Minister shall initiate a re-evaluation of that product no later than one year after 15 years have elapsed since the most recent decision of that type; and

(b) if the most recent decision of a type referred to in paragraph 28(1)(a) or (b) was made in relation to a pest control product before

Anciens titulaires

(6) L'obligation visée au paragraphe (5) d'établir et de conserver un registre des renseignements sur les ventes d'un produit antiparasitaire et de transmettre un rapport sur ces renseignements continue de s'appliquer à un ancien titulaire après que ce produit cesse d'être homologué.

…

Réévaluation

16 (1) Le ministre peut procéder à la réévaluation d'un produit antiparasitaire homologué s'il estime que, depuis son homologation, il y a eu un changement en ce qui touche les renseignements exigés ou la procédure à suivre pour l'évaluation de la valeur des produits de même catégorie ou de même nature ou des risques sanitaires ou environnementaux qu'ils présentent.

Réévaluation exigée

(2) Sans que soit limitée la portée générale du paragraphe (1) :

a) lorsqu'une décision sur l'homologation d'un produit antiparasitaire, du même type que celle visée aux alinéas 28(1)a) ou b), est prise le 1er avril 1995 ou après cette date, le ministre procède à une réévaluation du produit au plus tard un an après la période de quinze ans écoulée depuis la plus récente décision de ce type;

b) lorsque la plus récente décision sur l'homologation d'un produit antiparasitaire, du même type que celle visée aux alinéas 28(1)a) ou b),

April 1, 1995, the Minister shall initiate a re-evaluation of that product no later than April 1, 2005 or the date that is one year after 15 years have elapsed since that decision, whichever date is later.

a été prise avant le 1er avril 1995, le ministre procède à une réévaluation du produit au plus tard le 1er avril 2005 ou, si cette date est postérieure, la date qui suit d'un an la période de quinze ans écoulée depuis la décision.

Notice requesting information

(3) Re-evaluation of a pest control product is initiated by the Minister delivering a notice in writing to the registrant explaining the reasons for initiating the re-evaluation and, if considered necessary by the Minister, requiring the registrant to provide information in the form and within the period specified in the notice.

Demande de renseignements

(3) Le processus de réévaluation est enclenché par remise au titulaire, par le ministre, d'un avis écrit lui en expliquant les motifs et exigeant de lui, si le ministre l'estime nécessaire, qu'il fournisse des renseignements, en la forme et dans le délai qui y sont prévus.

Request for information from departments and provinces

(4) After the re-evaluation is initiated, the Minister shall deliver a notice to federal and provincial government departments and agencies whose interests and concerns are affected by the federal regulatory system requesting them to provide, in the form and within the period specified in the notice, information in respect of the health and environmental risks and the value of the product that is under re-evaluation.

Demande de renseignements — ministères et provinces

(4) Une fois le processus de réévaluation enclenché, le ministre remet aux ministères et aux organismes publics fédéraux et provinciaux dont les intérêts et préoccupations sont en jeu un avis leur demandant de fournir, en la forme et dans le délai qui y sont prévus, les renseignements relatifs aux risques sanitaires et environnementaux et à la valeur du produit visé.

Provision of information if more than one registrant

(5) If there is more than one registrant whose registered pest control products have active ingredients that the Minister has determined to be equivalent,

(a) two or more registrants may provide the information required

Fourniture de renseignements si plus d'un titulaire

(5) Lorsque le ministre a conclu que les principes actifs de produits homologués sont équivalents, les titulaires de ces produits peuvent fournir conjointement les renseignements exigés au paragraphe (3) ou à l'alinéa 19(1)a); s'il est convaincu que ces renseignements ont été fournis par l'un ou plusieurs de ces

under subsection (3) or paragraph 19(1)(a) jointly; and

(b) if the Minister is satisfied that the information required under subsection (3) or paragraph 19(1)(a) has been provided by one or more registrants, the Minister shall, subject to and in accordance with the regulations, permit another registrant to use or rely on that information to meet the requirements under that subsection or paragraph.

titulaires, le ministre permet, sous réserve des règlements et en conformité avec ceux-ci, à un autre de ces titulaires d'utiliser ces renseignements, ou de s'y fier, pour se conformer aux exigences prévues à ce paragraphe ou à cet alinéa.

If active ingredients not equivalent

(5.1) If the active ingredients of the registered pest control product that is subject to the re-evaluation are not equivalent to the active ingredients in another registrant's registered pest control product, the Minister shall, subject to and in accordance with the regulations, permit the registrant whose product is subject to the re-evaluation to use or rely on information provided by the other registrant if the Minister is satisfied that the information is necessary for the re-evaluation.

Principes actifs non équivalents

(5.1) Si les principes actifs d'un produit antiparasitaire homologué sujet à la réévaluation ne sont pas équivalents aux principes actifs d'un autre produit antiparasitaire homologué, le ministre permet, sous réserve des règlements et en conformité avec ceux-ci, au titulaire du produit sujet à la réévaluation d'utiliser les renseignements fournis par le titulaire de l'autre produit antiparasitaire homologué, ou de se fier à ces renseignements, s'il est convaincu que ces renseignements sont nécessaires à la réévaluation.

Evaluation of pest control product

(6) After the re-evaluation is initiated, the Minister shall, in accordance with the regulations, if any, conduct any evaluations that the Minister considers necessary with respect to the health or environmental risks or the value of the pest control product and shall carry out the consultations required by section 28.

Évaluation du produit

(6) Une fois le processus de réévaluation enclenché, le ministre procède, en conformité avec les éventuels règlements, aux évaluations qu'il juge nécessaires en ce qui concerne la valeur du produit ou les risques sanitaires ou environnementaux qu'il présente et procède aux consultations exigées par l'article 28.

***Pest Control Products Regulations*, SOR/2006-124**
***Règlement sur les produits antiparasitaires*, DORS/2006-124**

Application for Registration

Contents

6 (1) An application to register or amend the registration of a pest control product must include all of the following information:

(a) the applicant's name, address and signature or, if the application is made by a representative of the applicant, both the representative's and applicant's name and address and the representative's signature;

(b) the name and address of

(i) each place of manufacture of the pest control product, if it is or contains a microbial agent, and

(ii) each place of production and formulation of the pest control product, in any other case;

(c) the product name referred to in paragraph 26(1)(a);

(d) the product type referred to in paragraph 26(1)(b);

(e) the product's physical form referred to in paragraph 26(1)(c);

(f) the registration number referred to in paragraph 26(1)(i), if there is one;

(g) in the case of

(i) a chemical pest control product that is an active

Demande d'homologation

Contenu de la demande

6 (1) La demande d'homologation ou de modification d'homologation doit comporter les éléments suivants :

a) les nom et adresse du demandeur et sa signature ou, lorsque la demande est faite par un représentant du demandeur, outre les nom et adresse du demandeur, les nom et adresse du représentant et sa signature;

b) le nom et l'adresse :

(i) soit des établissements de fabrication du produit antiparasitaire, s'il s'agit d'un agent microbien ou si le produit antiparasitaire en contient un,

(ii) soit des établissements de production et de formulation du produit antiparasitaire dans tout autre cas;

c) le nom du produit visé à l'alinéa 26(1)a);

d) le type de produit visé à l'alinéa 26(1)b);

e) la forme physique du produit visée à l'alinéa 26(1)c);

f) le numéro d'homologation du produit visé à l'alinéa 26(1)i), s'il existe;

g) dans le cas :

ingredient, its chemical name, common chemical name and CAS registry number, its percentage of the total weight of the product in which it is contained, the name of each contaminant and other impurity that it contains, and the percentage of total weight of each contaminant and impurity,

(ii) a chemical pest control product other than an active ingredient, the chemical name, common chemical name and CAS registry number of each active ingredient in the product, each active ingredient's percentage of the total weight of the product, and the registration number of each active ingredient or other pest control product used to manufacture the product, and

(iii) any other pest control product, any characteristics that are relevant to its health or environmental risks or value;

(h) in the case of a pest control product that contains one or more formulants, the name of each formulant, its CAS registry number if any, its percentage of the total weight of the product and its purpose in the product;

(i) the size, type and specifications of the package in which the pest control product is to be distributed; and

(j) the statement described in paragraph 26(1)(h).

(i) du produit antiparasitaire chimique qui est un principe actif, son nom chimique, son nom chimique commun et son numéro d'enregistrement CAS, son pourcentage par rapport au poids total du produit qui le contient, le nom de chaque contaminant et autre impureté qu'il contient et le pourcentage de chaque contaminant et impureté par rapport au poids total du produit,

(ii) du produit antiparasitaire chimique autre qu'un principe actif, le nom chimique, le nom chimique commun et le numéro d'enregistrement CAS de chaque principe actif qu'il contient, le pourcentage de chaque principe actif par rapport au poids total du produit, ainsi que le numéro d'homologation de chaque principe actif ou autre produit antiparasitaire utilisé pour le fabriquer,

(iii) de tout autre produit antiparasitaire, les caractéristiques relatives aux risques sanitaires ou environnementaux ou à la valeur du produit;

h) dans le cas du produit antiparasitaire qui contient un ou plusieurs formulants, quant à chaque formulant : son nom et, le cas échéant son numéro d'enregistrement CAS, son pourcentage par rapport au poids total du produit, et son rôle dans le produit;

i) les dimensions, le type et les spécifications de l'emballage dans lequel le produit antiparasitaire doit être distribué;

j) l'énoncé visé à l'alinéa 26(1)h).

Electronic copy of label

(2) The applicant must include an electronic copy of the proposed label with every application to register a pest control product and with any application to amend the registration of a pest control product that would result in a change to the label.

Copie électronique de l'étiquette

(2) Le demandeur joint à la demande d'homologation une copie électronique de l'étiquette proposée pour le produit antiparasitaire. Il fait de même pour la demande de modification d'homologation, si celle-ci entraîne une modification de l'étiquette.

Certification

(3) The applicant must include with every application to register or amend the registration of a pest control product a statement signed by the applicant certifying that the information in the application is accurate and complete.

Demande exacte et complète

(3) Pour chaque demande d'homologation ou de modification d'homologation, le demandeur joint à la demande une attestation signée par lui portant que les renseignements qui figurent dans la demande sont exacts et complets.

…

…

Additional information required

8 In addition to the information required by section 6, the applicant must provide the Minister with any other information that the Minister may require to evaluate the health and environmental risks and the value of the pest control product, including, if relevant to the product and its conditions or proposed conditions of registration, the results of scientific investigations respecting any of the following:

(a) the efficacy of the pest control product for its intended purpose;

(b) the risks posed by the pest control product and its derivatives to humans or animals that may be

Autres renseignements

8 Le demandeur doit fournir au ministre, en plus des éléments visés à l'article 6, tous les autres renseignements exigés par celui-ci pour évaluer les risques sanitaires et environnementaux et la valeur du produit antiparasitaire. Ces renseignements comprennent, s'ils ont trait au produit et à ses conditions d'homologation proposées ou fixées, les résultats des recherches scientifiques effectuées sur ce qui suit :

a) l'efficacité du produit par rapport à l'utilisation à laquelle il est destiné;

b) les risques présentés par le produit et ses dérivés pour les humains ou les animaux qui peuvent y être exposés, notamment lors de la fabrication, de la

exposed to it, including when it is manufactured, handled, stored, transported or distributed or during or after its use or disposal, in accordance with its conditions or proposed conditions of registration;

(c) the effect of the pest control product and its derivatives on host organisms in connection with which it is intended to be used;

(d) the effect of the pest control product and its derivatives on representative species of organisms not targeted by its intended use;

(e) the degree of persistence, retention and movement of the pest control product and its derivatives in the environment, including the degree to which the pest control product and its derivatives may leach or dislodge from things treated with the product;

(f) methods of analysis for detecting the components and measuring the characteristics of the pest control product;

(g) methods of analysis for detecting and determining the amount of the pest control product and its derivatives in human food, animal feed and the environment when the product is used in accordance with its conditions or proposed conditions of registration;

(h) appropriate methods for detoxifying or neutralizing the pest control product in water, air or soil, or on any surface;

manipulation, du stockage, du transport ou de la distribution, ou pendant ou après l'utilisation ou l'élimination, conformément aux conditions d'homologation proposées ou fixées;

c) l'effet du produit et de ses dérivés sur les organismes hôtes en rapport avec lesquels il est destiné à être utilisé;

d) l'effet du produit et de ses dérivés sur des espèces représentatives d'organismes non visés par l'utilisation à laquelle il est destiné;

e) le degré de persistance, de rétention et de déplacement du produit et de ses dérivés dans l'environnement, y compris la mesure dans laquelle le produit et ses dérivés peuvent se lessiver ou se détacher des choses traitées avec celui-ci;

f) les méthodes d'analyse pour déceler les composants du produit et vérifier les caractéristiques de celui-ci;

g) les méthodes d'analyse pour déceler et déterminer la quantité du produit et de ses dérivés dans les aliments destinés à la consommation humaine ou animale, ainsi que dans l'environnement, lorsque le produit est utilisé conformément aux conditions proposées ou fixées pour son homologation;

h) les méthodes appropriées de détoxication ou de neutralisation du produit dans le sol, l'eau, ou l'air, ou sur toute surface;

(i) appropriate methods for disposing of the pest control product and its empty packages;

(j) the stability of the pest control product under normal conditions of storage and display;

(k) the compatibility of the pest control product with other pest control products with which it is recommended to be, or is likely to be, mixed;

(l) the effect of mixing the pest control product or using it simultaneously with other pest control products on its value and the health and environmental risks associated with its use;

(m) the chemical and physical properties, or the species or strain and biological properties, of the pest control product, its composition, and specifications and processes for its manufacture, including quality control processes;

(n) the fate of the pest control product in humans or animals exposed to it, including the identity and quantity of all the major metabolites and other derivatives that result from its use;

(o) the residues of the pest control product and its derivatives that may remain in or on human food or animal feed after its use in accordance with its conditions or proposed conditions of registration;

(p) the risks posed to humans or animals exposed to the pest control product or its derivatives through

i) les méthodes appropriées pour disposer du produit et de ses emballages vides;

j) la stabilité du produit dans les conditions normales de stockage et de présentation;

k) la compatibilité du produit avec d'autres produits antiparasitaires avec lesquels son mélange est recommandé ou se fera vraisemblablement;

l) l'effet que cause le mélange ou l'utilisation simultanée du produit avec d'autres produits antiparasitaires sur sa valeur et les risques sanitaires et environnementaux associés à son utilisation;

m) les propriétés chimiques et physiques du produit, ou son espèce ou sa souche et ses propriétés biologiques, sa composition, ainsi que ses spécifications et procédés de fabrication, y compris les processus d'assurance de la qualité;

n) le devenir du produit chez les humains ou les animaux qui y sont exposés, y compris l'identité et la quantité de tous les principaux métabolites et autres dérivés qui résultent de son utilisation;

o) les résidus du produit et de ses dérivés qui peuvent rester dans les aliments destinés à la consommation humaine ou animale ou sur ceux-ci, à la suite de son utilisation conformément à ses conditions d'homologation proposées ou fixées;

p) lorsque le produit est utilisé conformément à ses conditions d'homologation proposées ou fixées,

their diet or drinking water when the product is used in accordance with its conditions or proposed conditions of registration;

(q) the effect of storing and processing, including post-market processing, human food or animal feed in relation to which the pest control product was used on the dissipation or degradation of the pest control product and any of its derivatives;

(r) the proposed maximum residue limits for the pest control product and its derivatives in or on human food; and

(s) the fate of the pest control product and its derivatives in subsequent crops of human food or animal feed.

les risques présentés par celui-ci ou ses dérivés pour les humains ou les animaux qui y sont exposés par suite de l'ingestion d'aliments ou d'eau potable;

q) l'effet du stockage et de la transformation, y compris celle postérieure à la mise en marché, des aliments destinés à la consommation humaine ou animale en rapport avec lesquels le produit a été utilisé, sur la dissipation ou la dégradation de celui-ci et de ses dérivés;

r) les limites maximales de résidus proposées pour le produit et ses dérivés dans les aliments destinés à la consommation humaine ou sur ceux-ci;

s) le devenir du produit et de ses dérivés dans des cultures subséquentes d'aliments destinés à la consommation humaine ou animale.

…

…

Five-year periods

16 (1) 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.

Périodes de cinq ans

16 (1) Le titulaire peut demander au ministre de renouveler l'homologation d'un produit antiparasitaire pour des périodes maximales de cinq ans chacune.

Renewal applications

(2) An application to renew the registration of a pest control product must be accompanied by the following:

(a) the information required by subsection 6(1);

Demande de renouvellement

(2) La demande de renouvellement contient les renseignements et documents suivants :

a) les renseignements prévus au paragraphe 6(1);

(b) the statement required by subsection 6(3);

(c) the information required by section 8; and

(d) in the case of a registration certificate that was issued in the circumstances described in sections 17.7 to 17.94, a copy of the valid letter of access, as defined in section 17.1.

b) l'attestation visée au paragraphe 6(3);

c) les renseignements prévus à l'article 8;

d) s'il s'agit d'un certificat d'homologation délivré par suite de l'application du régime prévu aux articles 17.7 à 17.94, une copie de la lettre d'accès valide, au sens de l'article 17.1.

Request — labels

(3) The registrant must, if requested by the Minister, provide the Minister with an electronic copy of the approved label and two hard copies of the marketplace label.

Demande — étiquette

(3) Le titulaire fournit au ministre, sur demande de celui-ci, une copie électronique de l'étiquette approuvée et deux copies papier de l'étiquette de marché.