

Federal Court



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Date: 20250218

Docket: T-169-23

Citation: 2025 FC 300

Vancouver, British Columbia, February 18, 2025

PRESENT: The Honourable Mr. Justice Zinn

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

JUDGMENT AND REASONS

I. Overview

[1] This application is for judicial review of the decision by the Pest Management Regulatory Agency [PMRA or Agency] to renew the registration of Mad Dog Plus, a glyphosate-based

pesticide, for a five-year term pursuant to section 13 of the *Pest Control Products Regulations*, SOR/2006-124 [*Regulations*]. The Applicants, Friends of the Earth Canada, David Suzuki Foundation, Safe Food Matters Inc., and Environmental Defence Canada Inc., challenge the renewal decision on the basis that PMRA relied on dated risk assessments without properly considering new scientific evidence they submitted.

II. Background

A. *The parties*

[2] The Applicants are charitable, non-governmental organizations dedicated to protecting human health and the environment in Canada from pesticide risks. They meet the criteria for public interest standing necessary to bring this application for judicial review.

[3] The Respondent, the Attorney General of Canada, represents the Minister of Health [Minister], who oversees the PMRA. As a branch of Health Canada, the PMRA is responsible for registering and renewing pest control products in Canada under the *Regulations* and *Pest Control Products Act*, SC 2002, c 28 [*Act*]. Its mandate is to regulate pest control products in a way that safeguards the health and safety of Canadians.

[4] The Respondent Loveland Products Canada Inc. [Loveland] is the registrant of the pesticide Mad Dog Plus, which is registered for various agricultural and non-agricultural uses.

B. *Glyphosate in Canada*

[5] Glyphosate has been registered for use in Canada since the 1970s. It is the most heavily used pesticide active ingredient in Canada today, according to PMRA sales reports. Currently, there are over 169 registered pest control products containing glyphosate in Canada, authorized for various agricultural and non-agricultural uses.

[6] In 2015, the World Health Organization's International Agency for Research on Cancer [IARC] classified glyphosate and glyphosate end-use products as "probably carcinogenic." Between 2004 and 2017, PMRA conducted a re-evaluation of glyphosate's health and environmental risks under sections 17-21 of the *Act*. The Agency completed its analysis in 2015 and issued a proposed re-evaluation decision for public consultation on April 13, 2015. Following this consultation, the PMRA issued its final re-evaluation decision in 2017, concluding that glyphosate posed acceptable health and environmental risks and, contrary to the IARC's findings, was not carcinogenic. This decision allowed the continued registration of glyphosate products in Canada. The PMRA has repeated on several occasions that the re-evaluation considered both the active ingredient and formulated products, and it is based on reviews of hundreds of scientific documents, including information submitted by registrants and findings from scientific literature.

[7] Some of the Applicants have actively engaged with PMRA's glyphosate assessments. They participated in public consultations for re-evaluations, filed notices of objection to PMRA's 2017 re-evaluation decision, and followed through with litigation in the Federal Courts.

III. Facts

[8] On October 27, 2022, the Applicants sent a letter to PMRA, urging the Agency to suspend all renewals of glyphosate products until it has assessed the risks of glyphosate using updated science. The Applicants attached 61 new scientific studies identifying new or increased risks associated with glyphosate-based pesticides discovered since the 2017 re-evaluation. These risks included findings of increased toxicity in formulated products compared to glyphosate alone, potential hazards to human health through microbiome effects, evidence of neurodegenerative and reproductive toxicity, environmental risks to freshwater habitats, indications that glyphosate exacerbates wildfire risks, and additional ecological risks to wild pollinators.

[9] On August 8, 2022, Loveland applied to renew the registration of Mad Dog Plus. The PMRA did not require, and Loveland did not submit, any new data in support of the renewal. On December 28, 2022, PMRA renewed Loveland's registration for another five years.

[10] The PMRA responded to the Applicants' letter in February 2023, after this application for judicial review was filed. The Agency's response was that it was "aware of the scientific publications." It did not discuss any of the 61 studies or explain whether or how PMRA used this evidence to assess risks associated with Mad Dog Plus. It further reiterated that PMRA's assessment of the health and environmental risks of glyphosate is consistent with other international regulators and supported by the Incident Reporting Program.

[11] The Applicants sought production of PMRA's underlying assessments of the 61 new scientific studies through correspondence with counsel and a Rule 317 motion before this Court. Justice Fothergill granted that motion, specifically noting that the Court could not engage in meaningful judicial review without understanding PMRA's rationale: *Friends of the Earth Canada v. Canada (Attorney General)*, 2023 FC 1438 at para 20. In response to this production order, the Agency confirmed it had no documents "specifically prepared" regarding the renewal of Mad Dog Plus that addressed the 61 scientific publications. No further information was provided, and the Minister of Health did not submit an affidavit or any other explanation clarifying the lack of documented analysis.

IV. Decisions Below

[12] The PMRA provided no formal reasons for its December 2022 decision to renew the registration of Mad Dog Plus. However, the record reveals the decision-making process it followed. After Loveland submitted its renewal application in August 2022, the PMRA relied on its 2017 re-evaluation of glyphosate as the primary risk assessment baseline. This evaluation served as the foundation for any updates prompted by new evidence. When the Applicants later submitted their letter presenting new scientific studies alleging increased toxicity and environmental harm associated with glyphosate-based products, the PMRA conducted an internal review, which resulted in four brief memoranda.

[13] Three of these are internal memoranda produced by the Health Evaluation Directorate and Environmental Assessment Directorate. All of them contain near-identical language that acknowledge awareness of the new publications and state, without any elaboration, that the new

evidence “does not change the current assessment on file that risks are acceptable when label directions are followed.” The fourth is a memorandum issued by the Agency’s Incident Reporting Program, which analyzed 84 post-2017 incident reports involving glyphosate. This memorandum similarly concluded that “no serious health concerns or increasing health trends” had emerged, reaffirming that the PMRA’s prior baseline findings remained unchanged. This memorandum focused exclusively on incident data and provided no evaluation of the 61 scientific studies submitted by the Applicants.

[14] Beyond these four internal documents, the record contains no additional notes or analysis of the 61 articles. Relying on these internal materials, the PMRA renewed Mad Dog Plus for another five-year term. The “Renewal Registration Certificate” issued by the PMRA is a standardized form that primarily restates details from the application and confirms that the renewal was granted.

V. Issue

[15] The main issue for determination is whether PMRA’s December 2022 decision to renew the registration of Mad Dog Plus is reasonable. Specifically, the focus is on the Agency’s interpretation of statutory provisions governing renewal, its treatment of the new scientific evidence submitted by the Applicants, and the adequacy of its decision-making process as revealed by the record.

[16] Additionally, the parties ask the Court to determine the appropriate remedy, if the decision is found to be unreasonable.

VI. Standard of Review

[17] For substantive review, I agree with the parties that PMRA's renewal decision is reviewable on the standard of reasonableness, as articulated by the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*].

[18] When conducting a reasonableness review of decisions involving highly scientific and technical subject matters, courts must pay careful attention to the decision-maker's expertise: *Vavilov* at paras 92 and 93. This expertise warrants judicial deference in the assessment of facts: *Vavilov* at para 125; *Safe Food Matters Inc. v Canada (Attorney General)*, 2023 FC 1471 [*Safe Food Matters*] at para 121; *Dias v Canada (Attorney General)*, 2018 FCA 126 at para 8. Similarly, deference is warranted in the interpretation of law, particularly when it pertains to the decision-maker's home statutes: *Safe Food Matters* at paras 8 and 111; *Balogh v Canada (Citizenship and Immigration)*, 2022 FC 447 at para 18. However, as *Vavilov* makes clear, deference is contingent on the decision-maker demonstrating its expertise and is not to be presumed: *Vavilov* at para 93; *Mason v Canada (Citizenship and Immigration)*, 2023 SCC 21 [*Mason*] at para 70.

[19] Where, as in the present case, there are no formal written reasons, the reviewing court does not have a diminished obligation to conduct a robust reasonableness review, but the analysis necessarily shifts to evaluating the outcome and decision-making process to determine whether they align with the legal and factual constraints on the decision-maker: *Vavilov* at para 138. The court must adhere to the "reasons first" approach by examining the record and broader context to discern the decision-maker's rationale: *Vavilov* at para 137; *Mason* at para 69.

This requires the court to scrutinize the evidentiary record to reconstruct the reasoning process and ensure that statutory objectives are respected even where the reasoning is implicit. If the record and outcome reveal “dots on the page where the lines, and the direction they are headed, may be readily drawn,” reviewing courts may connect those lines: *Vavilov* at para 97, citing *Komolafe v Canada (Minister of Citizenship and Immigration)*, 2013 FC 431 at para 11.

However, reviewing courts must not create these dots to fill gaps in the decision-maker’s reasoning, particularly when the gaps involve failures to comply with key statutory mandates or grapple with significant evidentiary submissions: *Vavilov* at 96.

[20] The same approach applies to the decision-maker’s statutory interpretation. Even absent explicit reasons, courts must still assess whether the interpretation adopted is consistent with the text, context, and purpose of the statutory provision: *Vavilov* at para 120; *Mason* at para 69.

Regardless of the degree of discretion enjoyed by administrative decision-makers under their enabling statutes, their interpretation and application of statutory requirements must align with the legislative purpose: *Forbid Roads Over Green Spaces v Canada (Attorney General)*, 2023 FC 580 at paras 72-81. Administrative decision-makers in Canada hold no “absolute and untrammelled ‘discretion’”: *Roncarelli v Duplessis*, [1959] SCR 121 at page 140. Ultimately, for a decision without formal written reasons to be found reasonable, the decision-making process, reflected in the record and the outcome, must allow the reviewing courts to understand why the decision was made.

VII. Legal Framework

[21] The relevant provisions of the *Act* and *Regulations* can be grouped into four categories that collectively structure the various risk assessment mechanisms and the renewal process for pesticide registration. The full text of these provisions is appended to these Reasons.

[22] The first category articulates the legislative objective and risk assessment standard. Section 4(1) of the *Act* establishes the Minister's primary mandate is to "prevent unacceptable risks to individuals and the environment from the use of pest control products" when administering the *Act*. Subsection 2(2) of the *Act* defines the standard of "acceptable risk" as requiring "reasonable certainty that no harm to human health, future generations, or the environment will result from exposure to or use of the product."

[23] The second category establishes a framework for transparency and public accountability, with section 42 of the *Act* as its cornerstone. This section operationalizes the *Act*'s commitment to public awareness under paragraph 4(2)(c) by providing a mechanism for scrutinizing the scientific and regulatory rationale behind the PMRA's decisions. It mandates the establishment and maintenance of a publicly accessible Register of Pest Control Products, which serves as a repository of key information, including applications, registrations, re-evaluations, special reviews, and evaluation reports prepared by the Minister. To facilitate ongoing public oversight, the Register discloses non-confidential data, including active ingredients, registration conditions, and summaries of scientific evaluations, as provided in paragraph 42(2)(f) and subsection 42(4). However, section 42 does not require the creation or publication of new documents for renewal decisions.

[24] The third category contains four mechanisms through which risk assessments of pesticide registration might happen:

- 1) Initial Registration – When a pesticide is first registered, the Minister must conduct an assessment pursuant to section 7 of the *Act* to analyze risks to human health and the environment. Subsection 7(7) of the *Act* specifically requires that this assessment be conducted using a scientific approach. Approved products are then registered with specific conditions under subsection 8(1) of the *Act*.
- 2) Re-evaluation – Pursuant to section 16 of the *Act*, registered products must undergo a re-evaluation within a maximum of 15 years or sooner if warranted. This process involves a reassessment using more current scientific data and methodologies, and it may result in amendments to or cancellations of registrations.
- 3) Special Review – Under section 17 of the *Act*, the Minister must trigger a special review “if the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.” Such review involves a detailed assessment of emerging risks, such as those indicated by foreign regulatory actions or scientific studies, with potential for consultation and modifications to the product’s registration.
- 4) Renewal – While paragraph 8(1)(c) of the *Act* contemplates both finite and indefinite “validity period” of registration, section 13 of the *Regulations* imposes a five-year maximum term. The logical result of this is there must be a process for renewal.

[25] The fourth category details the operational framework of the renewal process, which is governed entirely by the *Regulations*. The primary provision of section 16 establishes the requirements for a renewal application. These include the information outlined in subsection 6(1), such as product composition, hazards, and safe use instructions, as well as a declaration under subsection 6(3) attesting to the accuracy and completeness of the application. Renewal applications must also include information that the Minister may require under section 8, including information on health and environmental risks, product value, and scientific investigations “relevant to the product and its conditions or proposed conditions of registration.”

VIII. Analysis

[26] The parties have advanced a variety of arguments pertaining to the reasonableness of PMRA’s decision. I find they converge to two core disputes. First, whether PMRA reasonably interpreted its statutory obligations under the *Act* and *Regulations* when considering renewal applications. Second, whether the PMRA sufficiently and transparently grappled with the Applicants’ submissions, namely the 61 new scientific articles.

A. *The PMRA’s interpretation of the renewal scheme is reasonable*

[27] The Applicants characterize the PMRA’s interpretation of the legislative framework as one that treats renewal decisions as purely administrative processes that neither consider new scientific evidence on health and environmental risks nor provide explanation of the rationale for its conclusions. According to the Applicants, this interpretation improperly confines substantive risk assessment exclusively to re-evaluation and special review processes.

[28] In opposition to this approach, the Applicants advance what they maintain is the only reasonable interpretation of the statutory and regulatory scheme governing renewal applications. The Applicants' interpretation builds on three main points.

[29] First, they contend that a combined reading of subsections 2(2), 4(1), 7(1), 8(4), and paragraph 8(1)(c) of the *Act* creates a clear obligation for the PMRA to ensure that risks remain acceptable before amending any registration term, including through renewal. This obligation, they argue, is further supported by the explicit powers granted under subsection 7(4) of the *Act* and section 8 and subsection 16(2) of the *Regulations*, which establish mandatory risk information requirements at the time of renewal.

[30] Second, the Applicants contend that the legislative choice of imposing finite registration periods in section 13 of the *Regulations*, coupled with substantive information requirements under subsection 16(2), necessarily establishes mandatory checkpoints where substantive risk assessments must occur. They argue that this interpretation is necessary to fulfill the legislation's goal of protecting Canadians' health and Canada's environment, especially given the documented delays in re-evaluation and special review processes that might otherwise leave unacceptable risks unaddressed for prolonged periods.

[31] Third, the Applicants contend that accepting the PMRA's interpretation would frustrate the protective purposes of the *Act* and render key provisions ineffective. They argue that the various provisions requiring risk information submissions and ongoing monitoring demonstrate Parliament's clear intent that renewals should involve substantive reviews incorporating new scientific evidence, rather than serving as mere administrative rubber stamps.

[32] I respectfully disagree with the Applicants' position. While their interpretation is plausible, it is not the only reasonable one. The PMRA's approach also falls within the range of reasonable interpretations following the modern principle of statutory interpretation.

[33] To begin, I will describe my understanding of the PMRA's interpretation of the legislative framework governing renewals based on the materials before me. Although the PMRA has provided no written reasons specific to this renewal, its interpretation of section 8 of the *Act* and sections 13 and 16 of the *Regulations* can be inferred from the decision-making process as revealed by the record and the outcome.

[34] In my view, the record indicates that the PMRA views the entire risk assessment and review framework as allowing for varying levels of scrutiny, contingent on the type of decision under the *Act* and *Regulations*. For renewal decisions specifically, the PMRA appears to have adopted a more streamlined, less intensive substantive review of risks. Two contextual observations support my characterization. First, the PMRA's reliance on the 2017 re-evaluation as the more comprehensive assessment suggests that it treats renewals as decisions informed by prior evaluations rather than as similar instances for new, full blown substantive analysis. Second, the PMRA's engagement with new scientific evidence through brief memoranda that confirm awareness of the information rather than through detailed analyses reflects a more selective and streamlined approach. In my view, these practices suggest the PMRA sees renewals as distinct checkpoints, separate from the more rigorous and substantive risk assessments performed during re-evaluations or special reviews.

[35] My characterization of the PMRA's approach finds further support in its stakeholder consultations regarding improvements on its risk assessment and product review programs. On June 21, 2022, the PMRA sent an email to the CEO of the Applicant, Friends of the Earth, attaching a PowerPoint document titled *Proposed Integrated Approach to Pesticide Evaluation* in preparation for a stakeholder consultation meeting the following day. In this document, the Agency describes its vision for an "expanded renewal process as a pulse check and consider information throughout the pesticide lifecycle" in addition to the usual safeguard of periodic re-evaluations. The slides acknowledge that full re-evaluations can be unwieldy, sometimes causing issues with substantive updates, delays, and protracted backlog. By contrast, the desired "expanded renewal process" allows the PMRA to consider, at more frequent intervals, whether "any emerging risk issues... require review," to identify what data might be needed in the future, and to consider taking action, such as initiating a special review, if new evidence raises alarm. While these consultation materials outline proposed future changes and do not, on their own, establish the PMRA's interpretation at the time of the decision six months later, I find that they provide useful context. Specifically, they reinforce the understanding that the Agency itself has been viewing renewals not as a mere "rubber stamping" formality, but as streamlined yet still substantive "pulse checks" that use newly available information to reassess the risk level of registered products up for renewal.

[36] I find this interpretation reasonable for several reasons. First, it stays alive to the operational realities the PMRA faces in regulating over 7,000 products at various stages of the registration cycle. Repeating the fulsome risk assessments performed at registration or re-evaluation for every renewal can impose paralyzing administrative burdens. Second, it respects how the *Act* structures different pathways for risk oversight: full or amended

registrations, re-evaluations, and special reviews require more rigorous consultation processes and mandatory formal reasons, whereas the renewal processes carry no such requirements. Third, it remains faithful to the protective purposes of the *Act*. If alarming new information arises, the PMRA can invoke the re-evaluation and special review mechanisms of the *Act* to conduct a full-scale substantive review. In tandem, subsection 16(2) and section 8 of the *Regulations* empower the PMRA to request additional information on a product and its risks. This discretion supports the interpretation that renewals by default involve a streamlined risk assessment process, with the operational flexibility to escalate to more comprehensive reviews if deemed necessary.

[37] Taken as a whole, I conclude that the PMRA's interpretation is reasonable. Contrary to the Applicants' contention, nothing in the *Act* and *Regulations* requires a *de novo* assessment each time a registration term nears its end. The PMRA's reading provides for a continuing oversight of product risks—an oversight that can escalate to include a more rigorous assessment if warranted—while avoiding unnecessary duplication of the thoroughness of a re-evaluation or special review at every renewal. Renewal, as the PMRA has understood and implemented it, is neither a mere rubber-stamping exercise, as the Applicants suggest the PMRA has done, nor a mandatory second round of rigorous and substantive re-evaluation, as the Applicants seem to demand. Instead, it is a reasonable, workable understanding of renewals as a streamlined checkpoint within a larger and layered regulatory system that provides different mechanisms for risk assessment for different situations.

B. *The PMRA's treatment of the Applicants' letter and scientific evidence is unreasonable*

[38] I now turn to the issue of whether the PMRA's handling of the Applicants' letter of October 27, 2022, particularly the 61 attached scientific studies, constituted a reasonable exercise of its expertise and discretion under the renewal regime.

[39] The Applicants' core contention is that the PMRA offered merely a bare assertion of "awareness" of new science, with no notes, logs, or underlying analysis to demonstrate how it weighed or tested that evidence. They say this leaves the reviewing court with the same "trust us, we got it right" problem identified in *Vancouver International Airport Authority v Public Service Alliance of Canada*, 2010 FCA 158 [*Vancouver International Airport Authority*] at paras 20–21. In their view, this absence of transparent reasoning is incompatible with the high protective standard set out in subsection 2(2) of the *Act*, which requires "reasonable certainty that no harm" will result.

[40] In particular, the Applicants emphasize the "serious new findings" found in the 61 studies, including indications of reproductive toxicity and enhanced dangers from glyphosate "formulations" rather than glyphosate alone. They characterize these findings as directly contradicting the PMRA's conclusions and argue that they should have been more transparently addressed. Because the PMRA's four internal documents do not even outline a cursory evaluation, no summary view of the studies as a whole or quick notes on thoughts about these articles, the Applicants submit the record is too opaque to allow for a meaningful reasonableness review. They assert that this is particularly problematic given the *Act's* focus on providing scientifically grounded and transparent justifications for regulatory decisions.

[41] The Applicants further argue that this opacity was further exposed by the Rule 317 order from Justice Fothergill, which compelled the PMRA to produce any specific assessment of the submitted studies. Despite initially resisting production, the Agency ultimately confirmed, after being ordered to comply, that it had no documents specifically addressing the 61 articles before renewing the product. The Applicants contend that this absence of documentation effectively prevents both them and this Court from determining whether, or to what extent, the new evidence was substantively reviewed.

[42] The Respondent, in both written submissions and oral argument, emphasizes that a renewal under the *Act* is intended as a streamlined administrative process rather than a formal, comprehensive re-evaluation. They note that the PMRA's 2017 re-evaluation of glyphosate was extensive, covering hundreds of scientific documents, and say the experts at the Agency remain continuously aware of current science. While acknowledging that the four internal memoranda are terse, the Respondent insists they are sufficient to show that PMRA scientists "did look at" the 61 new articles and concluded none warranted altering the existing acceptable-risk finding. Furthermore, the Respondent stresses that no specific statutory provision obliges the PMRA to publish detailed reasoning at renewal, pointing to the *Act*'s clear distinction between routine renewals and full-scale re-evaluations or special reviews, which do mandate more elaborate analysis and public engagement.

[43] When asked by this Court how the PMRA's decision could be reviewed without any record of how the 61 studies were examined, which potentially leaves the Court with nothing more than the Respondent's assurance of "trust us, we got it right," counsel responded that the governing scheme contemplates a lighter form of scrutiny for renewals. The Respondent argued

that “no formal reasons” are required and that *Vavilov* permits a reviewing court to glean rationale from the record. They maintained that deferring to the PMRA’s scientific expertise is especially apt here because the Agency determined that the new studies simply did not “move the needle” considering the robust 2017 re-evaluation. When pressed on whether the available material was sufficient to confirm that a genuine review had taken place, given the absence of any written engagement with the Applicants’ evidence, counsel insisted that the short memos, plus the PMRA’s proven track record of ongoing monitoring, collectively meet *Vavilov*’s reasonableness requirement.

[44] I agree with the Applicants. While I accept that the PMRA’s interpretation of renewals as involving a more limited risk assessment is reasonable, I do not see how a valid “streamlined” approach can eliminate the need for a transparent and intelligible rationale. This is particularly true when the Applicants have provided new, specific, and allegedly contradictory health and environmental evidence from recent scientific research. Deference to administrative decision-makers on technical and scientific matters is not warranted when they have grappled with the Applicants’ core submission in only a superficial manner, if at all. Although *Vavilov* allows me to infer reasoning from the record and outcome in the absence of formal written reasons, I cannot deem a decision reasonable when the record offers virtually no sign of whether the Agency has considered evidence that directly challenges its conclusions. All the record shows me are mere unsubstantiated assurances communicated through standardized language. Simply put, I cannot connect the dots when there are none.

[45] The situation at hand bears many similarities to that in *Catalyst Pharmaceuticals, Inc. v Canada (Attorney General)*, 2021 FC 505. In that case, Justice St-Louis found that the

administrative record at hand failed to show any meaningful trace of how Health Canada considered the applicant's data protection rights, or whether it assessed the regulatory framework governing such protections. Justice St-Louis emphasized that a record lacking transparency offers no discernible insight into whether the relevant materials were meaningfully considered, making it fundamentally incompatible with meaningful judicial review. An opaque or skeletal record, in essence, prevents the reviewing court from determining whether the decision-maker properly engaged with the key requirements laid out by the legislative framework.

[46] In this case, all we see are four internal PMRA documents asserting the new evidence does not change the existing assessment. There is no indication of any log or short summary recording the reviewing scientists' considerations of the new evidence, even if very briefly. Indeed, the memoranda and incident report do not substantively address any studies at all, they merely acknowledge their existence, despite the gravity of the concerns flagged by the Applicants. This leaves the Court unable to determine whether the PMRA genuinely weighed the new data against the existing risk assessment or merely acknowledged the Applicants' submission as a procedural formality.

[47] Furthermore, while one of the PMRA's documents referenced the 84 post-2017 incident reports and concluded that there were no concerning trends, this document alone cannot justify the lack of any documented engagement with 61 separate pieces of scientific scholarship. Although monitoring incident reports demonstrates the PMRA's efforts to stay informed of recent developments in the field, these reports are categorically different from the scientific studies provided in the Applicants' letter. The incident reports may intersect with, overlap, or

even contradict the Applicants' scientific evidence, yet the record does not clarify whether or how the analysis of these incident reports was integrated into the review of the Applicants' evidence. The PMRA might well have had valid reasons to discount or set aside the new material, but the record does not reveal them. In my view, this lack of transparency reflects exactly the "trust us, we got it right" approach that is incompatible with the principles set out in *Vavilov*.

[48] The Respondent urges that the Court should defer to the PMRA's "recognized expertise, the significant review undertaken during the re-evaluation, the thousands of pest control products that PMRA regulates, and the nature of a renewal decision." I agree that the legislative framework likely does not require a full-scale re-evaluation or special review each time new data is submitted at the renewal stage. But the complete absence of any notes, logs, or even a brief summary outlining the PMRA's thought process regarding the Applicants' evidence means its decision fails to meet the legal standard of reasonableness. As the Federal Court of Appeal emphasized in *Vancouver International Airport Authority* at paragraph 25, administrative decision-makers can "address fundamental purposes" with only "a sentence or two" per study or even category of evidence. Where administrative expertise is not demonstrated, deference is not warranted: *Vavilov* at paras 92 and 93.

[49] I also reject that asking the PMRA to provide brief explanations of the Applicants' evidence would impose the overwhelming operational burden described by the Respondent, even considering the Agency's daily responsibilities. As I noted during the hearing, if the scientists genuinely reviewed 61 new studies, they must have formed some reasoning as to why those

studies did not raise concerns. I agree with the Applicants that a scientifically based conclusion must inherently include a rationale, as the very nature of scientific inquiry demands a logical path from evidence to conclusion. This is fundamental to the scientific method's core principles of testability, reproducibility, and peer review. Recording a few lines to document relevant reasoning in a format convenient for the reviewing scientists would hardly be onerous if the reviewers have indeed turned their mind to the studies submitted by the Applicants. I am not expecting a detailed rationale akin to a court decision, nor an exhaustive meta-analysis or systematic literature review to justify why the Applicants' studies do not warrant further scrutiny. Arbitrating scientific truth is not this Court's role—it is the role of the PMRA. Yet, this Court does require some indication of genuine analysis in the record to demonstrate that the PMRA meaningfully grappled with the Applicants' evidence. We do not see that here. Without it, there is no discernible chain of reasoning, as required by *Vavilov*.

[50] It follows that the PMRA's approach here fails on transparency and justifiability grounds, rather than on a misinterpretation of the *Act* and *Regulations*. The PMRA's statutory interpretation that a renewal is not a second re-evaluation or special review is defensible, but its application of its interpretation in this case precludes meaningful scrutiny. The four internal documents in the record do not do so. Each, in my view, reads more like a generic statement of "no change," offering no clue how 61 separate studies were weighed, tested, or rejected. In short, the PMRA's implementation of its own renewal approach here leaves no path forward for reasonableness review.

C. *The appropriate remedy is to remit the matter for redetermination with delayed quashing*

[51] Beyond asking this Court to set aside the renewal of Mad Dog Plus, the Applicants also seek a declaration that would establish their more stringent interpretation of the renewal scheme as binding. The Respondents, by contrast, request that any remedial order only remit the decision to the PMRA for reconsideration, without a declaratory ruling.

[52] I decline to make the Applicants' requested declaration. As discussed, I find the PMRA's underlying view that renewals do not require a complete re-evaluation to be reasonable. The flaw in this case arises not from that interpretation but from the PMRA's application of it. Hence, there is no need for a binding pronouncement in the manner the Applicants propose.

[53] Turning to whether I should also quash the renewal, counsel for Loveland raised concerns during oral submissions about the potentially severe consequences of outright invalidation. Among other things, losing the renewal status could subject Loveland to liability under section 32 of the *Act*, should the product be sold or distributed without valid registration. That provision exposes registrants to fines ranging from \$200,000 upon summary conviction to \$500,000 on indictment, as well as possible imprisonment.

[54] I find Loveland's arguments persuasive in the present circumstances. Mad Dog Plus is but one glyphosate-based product among many similarly renewed by the PMRA. It would be disproportionately onerous to force Loveland, and all parties in its distribution chain, to endure an abrupt invalidation of the renewal, pending reconsideration, particularly given that the

statutory breach at issue is the PMRA's lack of transparent reasons rather than Loveland's wrongdoing.

[55] However, I also find that maintaining the renewal indefinitely without sufficient justification would undermine regulatory accountability. The PMRA's failure to provide a meaningful explanation regarding the 61 new scientific studies cannot be overlooked. To balance these concerns, I remit the matter to the PMRA for redetermination in accordance with these Reasons, without quashing the renewal immediately. The decision under review shall be quashed on the date that is the earlier of the date that is six months from the date hereof, or the date the Agency provides a decision in accordance with these Reasons on the redetermination. Should additional time be required, the issue may be put to me with reasons why the time provided was insufficient. This approach ensures accountability while avoiding immediate disruption to Loveland and downstream users.

IX. Conclusion

[56] I conclude that the PMRA's interpretation that renewals under the *Act* and *Regulations* serve as a streamlined checkpoint distinct from a full re-evaluation is reasonable. Nothing in the relevant provisions requires a *de novo*, substantive risk assessment whenever a registration term expires, provided the PMRA retains sufficient flexibility to escalate its review when presented with compelling new evidence.

[57] However, the PMRA's application of that interpretation in this case is unreasonable. The record offers no meaningful insight into how the PMRA considered the 61 new scientific studies the Applicants submitted, if it gave them any consideration at all. This leaves this Court

with a “trust us, we got it right” stance incompatible with *Vavilov*. Brief and conclusory internal documents indicating mere “awareness” of the evidence do not meet the “justification, transparency, and intelligibility” threshold necessary for reasonableness review.

[58] As for remedy, I decline to issue the Applicants’ requested declaration. The Applicants’ proposed interpretation is not the only reasonable one allowed by the statutory scheme. The PMRA’s “streamlined” reading of renewals is also reasonable. Further, I accept Loveland’s submission that quashing the renewal decision entirely would cause overly harsh consequences, potentially exposing the registrant to liability under section 32 of the *Act* and abruptly disrupting supply chains.

[59] Therefore, I remit the matter to the PMRA without immediately quashing the renewal. The Agency must revisit its decision on Mad Dog Plus, and within six months provide an intelligible explanation, consistent with these Reasons, of how it weighs the Applicants’ 61 studies before confirming whether the existing acceptable-risk conclusion should remain in place. In doing so, nothing prevents the PMRA from maintaining its current outcome if, upon a more transparent review, it still finds the new evidence unpersuasive. However, it must supply a minimal level of rationale sufficient to permit meaningful judicial scrutiny under *Vavilov*.

[60] Accordingly, I grant the judicial review application in part: the PMRA’s decision is found unreasonable, but the renewal stands for only six months pending the PMRA’s redetermination.

[61] Each party shall bear their own costs, as requested.

JUDGMENT in T-169-23

THIS COURT'S JUDGMENT is that this application is allowed, in part:

1. The renewal decision under review is not reasonable;
2. The Pest Management Regulatory Agency is to redetermine the renewal within six months of this decision, in accordance with these Reasons;
3. The decision under review shall be quashed on the date that is the earlier of the date the Pest Management Regulatory Agency completes the redetermination in accordance with these Reasons, or the date that is six months from the date hereof, unless an extension is ordered as provided in these Reasons; and
4. No costs are awarded.

"Russel W. Zinn"

Judge

APPENDIX*Pest Control Products Act, SC 2002, c 28***Acceptable risks**

2 (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.

...

Mandate**Primary objective**

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.

...

Registration of Pest Control Products**Applications for Registration or Amendment****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.

Risques acceptables

2 (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.

[...]

Mission**Objectif premier**

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.

[...]

Homologation des produits antiparasitaires**Demande d'homologation ou de modification d'homologation****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.

Use of information provided by registrants

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

7 (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 the value of the pest control product;

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 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

7 (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;

(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.

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.

Denial of application

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

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 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

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.

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.

Refus de donner suite

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

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 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) 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

(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

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, 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

determined that a different margin of safety would be appropriate.

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.

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.

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

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) specifying the conditions relating to its manufacture, handling, storage, transport, import, export, packaging, distribution, use or disposition, including conditions relating

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

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.

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.

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).

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.

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 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.

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).

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).

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.

...

Re-evaluation and Special Review**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

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).

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 et examen spécial**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

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 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.

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.

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.

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,

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), 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.

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.

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.

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

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

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.

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.

Initiation of special review by Minister

17 (1) The Minister shall initiate a special review of the registration of a pest control product if the Minister has reasonable grounds to believe that the health or

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 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.

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.

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.

Examen spécial

17 (1) Le ministre procède à l'examen spécial de l'homologation du produit antiparasitaire lorsqu'il a des motifs raisonnables de croire que la valeur du produit ou les risques

environmental risks of the product are, or its value is, unacceptable.

Special review where OECD ban

(2) Without limiting the generality of subsection (1), when a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the Minister shall initiate a special review of registered pest control products containing that active ingredient.

Special review where information from department or province

(3) Without limiting the generality of subsection (1), the Minister shall initiate a special review of the registration of a pest control product if a federal or provincial government department or agency has provided information to the Minister that relates to the health or environmental risks or the value of the product and if, after considering the information provided, the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.

Request for special review

(4) Any person may request a special review of the registration of a pest control product by making a request to the Minister in the form and manner directed by the Minister.

Decision

(5) Within a reasonable time after receiving a request, the Minister shall decide whether to initiate a special review and shall respond to the request with written reasons for the decision.

sanitaires ou environnementaux qu'il présente sont inacceptables.

Examen spécial — interdiction de l'OCDE

(2) Sans que soit limitée la portée générale du paragraphe (1), lorsqu'un pays membre de l'Organisation de coopération et de développement économiques interdit l'utilisation d'un principe actif pour des raisons sanitaires ou environnementales, le ministre procède à l'examen spécial des produits antiparasitaires homologués contenant ce principe actif.

Examen spécial — renseignements des ministères ou provinces

(3) Sans que soit limitée la portée générale du paragraphe (1), le ministre procède à l'examen spécial de l'homologation du produit antiparasitaire lorsqu'un ministère ou organisme public fédéral ou provincial lui fournit les renseignements relatifs aux risques sanitaires ou environnementaux ou à la valeur du produit visé et, à la suite de l'étude de ces renseignements, le ministre a des motifs raisonnables de croire que la valeur du produit ou les risques sanitaires ou environnementaux qu'il présente sont inacceptables.

Demande

(4) Toute personne peut faire une demande d'examen spécial au ministre, en la forme et de la façon qu'il précise.

Décision

(5) Dans un délai raisonnable suivant la réception de la demande, le ministre décide s'il procède ou non à l'examen et communique à son auteur sa décision en la motivant par écrit.

Scope of special review

(6) For the purposes of this section, the Minister shall initiate a special review only in relation to the aspect of the pest control product that prompted the special review.

Addition of aspect

(7) If the Minister has initiated a re-evaluation of, or a special review in relation to, a pest control product, the Minister may, at any time before the decision statement is made public under subsection 28(5), expand the scope of the re-evaluation or special review to include any aspect of the product that would otherwise prompt a new special review under subsection (1), (2) or (3).

New or amended consultation statement

(8) If the Minister expands the scope of a re-evaluation or special review under subsection (7) after the consultation statement relating to the re-evaluation or special review has been made public under subsection 28(2), the Minister shall make public a new or amended consultation statement under that subsection that takes into account the aspect referred to in subsection (7).

Discretion of Minister — aspect already covered

17.1 (1) Despite section 17, the Minister may decide not to initiate a special review in relation to a pest control product if a re-evaluation of, or a special review in relation to, the product has already been initiated that includes the aspect of the product that would otherwise prompt a special review.

Portée de l'examen spécial

(6) Pour l'application du présent article, le ministre procède à l'examen spécial uniquement relativement à l'aspect du produit antiparasitaire qui justifie l'examen spécial.

Ajout d'un aspect

(7) S'il a déjà procédé à une réévaluation d'un produit antiparasitaire ou à un examen spécial relatif à un tel produit, le ministre peut, à tout moment avant de rendre public l'énoncé de décision visé au paragraphe 28(5), étendre la portée de la réévaluation ou de l'examen spécial à l'aspect du produit qui aurait justifié un nouvel examen spécial au titre des paragraphes (1), (2) ou (3).

Énoncé de consultation nouveau ou modifié

(8) S'il étend la portée d'une réévaluation ou d'un examen spécial au titre du paragraphe (7) après avoir rendu public l'énoncé de consultation relatif à la réévaluation ou à l'examen spécial au titre du paragraphe 28(2), le ministre rend public au titre de ce paragraphe un énoncé de consultation nouveau ou modifié qui tient compte de l'aspect visé au paragraphe (7).

Discretion du ministre — aspect déjà couvert

17.1 (1) Malgré l'article 17, le ministre peut décider de ne pas procéder à l'examen spécial relatif au produit antiparasitaire si l'aspect du produit qui aurait justifié l'examen spécial est déjà visé par une réévaluation du produit ou un examen spécial relatif au produit.

Discretion of Minister — previous decision statement

(2) Despite subsection 17(2), the Minister may decide not to initiate a special review of a registered pest control product under that subsection if

(a) the Minister made public under subsection 28(5) a decision statement respecting a re-evaluation of, or a special review in relation to, that product;

(b) the aspect of the product that would otherwise prompt a special review was addressed by the re-evaluation or special review referred to in paragraph (a); and

(c) the Minister determines that there is no additional information in relation to the health or environmental risks of the product that provides the Minister with reasonable grounds to believe that those risks are unacceptable.

Duty to make decisions public

17.2 The Minister shall make public each of the following decisions and the reasons for it:

(a) a decision made under subsection 17(7) to expand the scope of a re-evaluation or special review to include an aspect that would otherwise prompt a new special review under subsection 17(2);

(b) a decision made under subsection 17.1(1) or (2) not to initiate a special review in relation to an aspect that would otherwise prompt such a review under subsection 17(2).

Discrétion du ministre — énoncé de décision

(2) Malgré le paragraphe 17(2), le ministre peut décider de ne pas procéder à l'examen spécial du produit antiparasitaire homologué au titre de ce paragraphe si :

a) il a rendu public un énoncé de décision au titre du paragraphe 28(5) en ce qui a trait à la réévaluation du produit ou à l'examen spécial relatif au produit;

b) l'aspect du produit qui aurait justifié l'examen spécial était visé par la réévaluation ou l'examen spécial visé à l'alinéa a);

c) il conclut qu'il n'y a pas de renseignements supplémentaires au sujet de risques sanitaires ou environnementaux que présente le produit qui feraient en sorte qu'il aurait des motifs raisonnables de croire que ces risques sont inacceptables.

Obligation de rendre publiques les décisions du ministre

17.2 Le ministre rend publiques les décisions ci-après ainsi que les motifs de celles-ci :

a) les décisions prises au titre du paragraphe 17(7) d'étendre la portée d'une réévaluation ou d'un examen spécial à l'aspect qui aurait justifié un nouvel examen spécial au titre du paragraphe 17(2);

b) les décisions prises au titre des paragraphes 17.1(1) ou (2) de ne pas procéder à un examen spécial relatif à l'aspect qui aurait justifié un tel examen au titre du paragraphe 17(2).

*Pest Control Products Regulations, SOR/2006-124***Application for Registration****Demande d'homologation****Contents****Contenu de la demande**

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

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

(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;

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) the name and address of

b) le nom et l'adresse :

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

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

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

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

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

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

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

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

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

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

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

(g) in the case of

g) dans le cas :

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

(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

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).

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.

Certification

(3) The applicant must include with every application to register or amend the

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).

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.

Demande exacte et complète

(3) Pour chaque demande d'homologation ou de modification d'homologation, le

registration of a pest control product a statement signed by the applicant certifying that the information in the application is accurate and complete.

...

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 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

demandeur joint à la demande une attestation signée par lui portant que les renseignements qui figurent dans la demande sont exacts et complets.

[...]

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 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

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;

(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;

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 détoxification ou de neutralisation du produit dans le sol, l'eau, ou l'air, ou sur toute surface;

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) 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 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.

...

Validity Period

Maximum validity period

13 The validity period of a registration of a pest control product must end no later than

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, 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.

[...]

Période de validité

Période maximale

13 La période de validité de l'homologation d'un produit antiparasitaire se termine au plus

December 31 in the fifth year after the year in which the product is registered.

...

Renewal of Registration

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.

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);

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

(c) the information required by section 8;

(d) if sections 17.05 to 17.11 apply, whichever of the following documents is applicable:

(i) a document that establishes that, as of the date the application is made, a negotiated settlement between the registrant and the data holder has been reached or an arbitral award has been made in respect of the test data and the data holder has not provided a letter of access referred to in section 17.1 to the registrant, or

(ii) a copy of the letter of access referred to in section 17.1; and

tard le 31 décembre de la cinquième année qui suit l'année d'homologation.

[...]

Renouvellement de l'homologation

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.

Demande de renouvellement

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

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

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

c) les renseignements prévus à l'article 8;

d) celui des documents ci-après qui s'applique, si les articles 17.05 à 17.11 s'appliquent :

(i) un document établissant que, à la date de la présentation de la demande, le titulaire et le détenteur de données ont conclu un règlement négocié ou une décision arbitrale a été rendue à l'égard des données d'essai et le détenteur de données n'a pas fourni au titulaire la lettre d'accès visée à l'article 17.1,

(ii) une copie de la lettre d'accès visée à l'article 17.1;

(e) if sections 17.12 to 17.17 apply, whichever of the following documents is applicable:

(i) a document that establishes that, as of the date the application is made,

(A) the registrant and data holder are negotiating the compensation payable in respect of the test data,

(B) the determination of the compensation payable in respect of the test data has been submitted to binding arbitration and an arbitral award has not been made, or

(C) a negotiated settlement between the registrant and the data holder has been reached or an arbitral award has been made in respect of the test data and the data holder has not provided a letter of access referred to in section 17.17 to the registrant, or

(ii) a copy of the letter of access referred to in section 17.17.

Interpretation — data holder and test data

(2.1) In subsection (2), data holder and test data have the same meanings as in section 17.01.

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.

e) celui des documents ci-après qui s'applique, si les articles 17.12 à 17.17 s'appliquent :

(i) un document établissant que, à la date de la présentation de la demande, selon le cas :

(A) le titulaire et le détenteur de données d'essai négocient les droits à payer pour celles-ci,

(B) l'établissement des droits à payer pour les données d'essai a été soumis à l'arbitrage obligatoire et la décision arbitrale n'a pas été rendue,

(C) le titulaire et le détenteur de données d'essai ont conclu un règlement négocié ou une décision arbitrale a été rendue à l'égard des données d'essai et le détenteur de données n'a pas fourni au titulaire la lettre d'accès visée à l'article 17.17,

(ii) une copie de la lettre d'accès visée à l'article 17.17.

Interprétation — détenteur de données et données d'essai

(2.1) Au paragraphe (2), détenteur de données et données d'essai s'entendent au sens de l'article 17.01.

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.

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-169-23

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