Court File No. A-85-20

FEDERAL COURT OF APPEAL

B E T W E E N:

SAFE FOOD MATTERS INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

and

DAVID SUZUKI FOUNDATION, ENVIRONMENTAL DEFENCE CANADA INC. and FRIENDS OF THE EARTH CANADA/ LES AMIS DE LA TERRE

Interveners

APPLICATION UNDER subsection 18.1(1) of the Federal Courts Act, R.S.C. 1985, c. F-7, as amended

MEMORANDUM OF FACT AND LAW OF THE APPELLANT

December 4, 2020

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PART I - OVERVIEW

1. This is an appeal from a Federal Court judgment dismissing an application for judicial review of a decision under the *Pest Control Products Act*[1] ("**PCPA**") and its regulations, which create a comprehensive regulatory regime for pesticide registration and use in Canada. The use of pesticides can pose risks to human health, the environment and future generations. As a result, the primary objective of the PCPA is to "prevent unacceptable risks to individuals and the environment from pest control products".[2] In this appeal the Court has the opportunity to pronounce for the first time on legal standards designed to achieve that objective.

2. Glyphosate, a pesticide, is the active ingredient in Roundup and other pest control products. It was first registered for use in Canada in 1976 and has been continuously registered since then. Health Canada conducted a re-evaluation under the PCPA of the risks and value of glyphosate products. In 2017, the Pesticide Management Regulatory Agency ("**PMRA**") issued a re-evaluation decision permitting the registration of glyphosate products for use in Canada to continue.

3. Glyphosate is widely-used on food crops consumed by Canadians. It can be used to kill weeds, but can also be used to dry down or "desiccate" a crop for harvest by killing it just prior to harvest, a practise known as pre-harvest management. However, research shows that when crops are desiccated when the crop is not yet mature physiologically, glyphosate will accumulate at higher levels in the seeds being produced by that crop. The accumulation of glyphosate residues in these seeds, which are the beans, grains or seeds consumed by Canadians, poses health concerns.

4. The PCPA permits public participation following issuance of a re-evaluation decision by allowing members of the public to raise objections to the decision. Pursuant to the process in the PCPA, the Appellant filed a notice of objection to the PMRA's re-evaluation decision. The notice of objection raised nine objections, which included three main arguments with supporting evidence: first, that the re-evaluation did not examine one way that glyphosate gets into food; second, that Canadians might be exposed to glyphosate in food at levels greater than those considered in the re-evaluation; and third, that the measures proposed by PMRA to mitigate the risks will not work in all cases. The Appellant asked the PMRA to exercise its statutory

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[1] SC 2002, c 28.
[2] **PCPA**, s 5.

discretion to appoint a review panel of expert scientists to examine and advise on the issues identified in the notice of objection.

5. The PMRA dismissed the notice of objection and refused to appoint an independent panel to review the re-evaluation decision. The Appellant submits that the PMRA did not act within the legal and factual constraints limiting the exercise of its discretion, and that its decision did not meet even the minimum standards of justification, transparency and intelligibility.

6. The Appellant applied for judicial review, asking the court to quash the PMRA's decision and order the PMRA to establish a review panel. The Federal Court dismissed the application after arriving at its own interpretation of the legislation and using that interpretation to support the outcome reached by the PMRA, instead of focussing on the reasonableness of the PMRA's decision in light of the reasons given and the relevant factual and legal constraints. The Federal Court's approach was wrong in law.

7. On a proper application of the reasonableness standard of review as laid out by the Supreme Court of Canada in *Vavilov*,[3] and re-affirmed by this Court in subsequent decisions, the PMRA's decision cannot stand. The Appellant asks this Court to allow its appeal and to quash the PMRA's decision.

PART II - STATEMENT OF FACTS

A. Background

8. The PMRA is a branch of Health Canada. It been delegated the responsibilities of the Minister of Health for regulation of pest control products ("**PCPs**") in Canada, and regulates them under the authority of the PCPA. A PCP is a product used for pest control. A pest is a troublesome plant, animal or other organism: in essence, a weed, fungus or a bug.[4] PCPs must be closely regulated because, as stated in the preamble to the PCPA, they "pose potential risks, both directly and indirectly, to the health, safety and well-being of individuals in Canada and to the environment." The main purpose of

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[3] ***Canada (Minister of Citizenship and Immigration) v Vavilov***, 2019 SCC 65, Appellant's BoA, Tab 1.
[4] **PCPA**, s 2(1): "pest means an animal, a plant or other organism that is injurious, noxious or troublesome, whether directly or indirectly, and an injurious, noxious or troublesome condition or organic function of an animal, a plant or other organism".

the PCPA is to "prevent unacceptable risks to individuals and the environment from the use of pest control products"[5].

9. The basic scheme under the PCPA is as follows: on an application for registration, a PCP are assessed for risks to human health and the environment by PMRA; if the PMRA grants registration, the PCP is registered in a database; and post-registration, PCPs are re-evaluated periodically. An applicant seeking registration of a PCP must submit relevant studies and appropriate scientific information to assist the PMRA in its evaluation of the PCP's risks. The Act provides a number of opportunities for members of the public to participate in the regulatory scheme, including by bringing forward to the PMRA their objections to decisions permitting registration of certain PCPs. The PCPA also provides for decisions to be re-considered, for access to information, and for enforcement.

10. When PCPs are used for agricultural purposes, dietary risks to human health arise from the fact that PCPs leave residues on and in the crops to which they are applied. Therefore, when the PMRA evaluates a PCP it must consider available information on, (among other things) aggregate exposure to the PCP through dietary exposure.[6] In deciding to register a PCP, the Minister is required, "if necessary" to specify the maximum limits of pesticide residue that the Minister considers appropriate.[7] These are referred to in the PCPA as "maximum residue limits" ("**MRLs**"). PMRA describes MRLs as "are an essential part of ensuring that the dietary intake of pesticide does not lead to unacceptable exposure and risks to human health."[8] MRLs may also be specified for unregistered products, or for a registered PCP with respect to a use that is not provided for by its registration[9] (referred to as a User-Requested Minor-Use Label Expansion or "**URMULE**").

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[5] **PCPA**, s. 4(1).
[6] **PCPA**, s. 11.
[7] **Section 9 of the PCPA** provides: "When making a decision regarding the registration of a pest control product, the Minister shall, if necessary, specify any maximum residue limits for the product or for its components or derivatives that the Minister considers appropriate in the circumstances." While the Minister must specify a MRL for registered products, she "may" specify a MRL for unregistered products or uses of a registered product not provided for by the registration: **PCPA, s. 10**.
[8] **Technical Paper SPN2000-01**, published by PMRA, December 22, 2000 at 15 ("SPN2000-01"), Exhibit "B" to the **Affidavit of Mary Lou McDonald**, affirmed April 18, 2019 ("McDonald Affidavit"), Appeal Book, Tab 6B, p 160; **McDonald Affidavit**, para 5, Appeal Book, Tab 6, p 67.
[9] **PCPA**, s 10.

B. Pre-harvest use and registration of glyphosate

11. Glyphosate is a non-selective systemic herbicide. "Non-selective" means it is not selective as to what plants it kills, and "systemic" means it enters the plant and moves throughout its entire system. In addition to weed control uses, the Minister has registered various glyphosate products for pre-harvest management use, at least in part because of its utility as a crop desiccant. Agricultural producers spray glyphosate on crops to dry down and kill the plants, which facilitates harvesting.[10]

12. When glyphosate is applied to a plant, it penetrates into the plant's growing systems. It migrates to areas of the plant in which nutrients (including sugars) concentrate, *i.e.* the fruits, grains, beans and seeds the plant produces. This movement to the growing parts of a plant is referred to as "**translocation**". As explained by one weed specialist (who advises against using glyphosate as a desiccant):

> Glyphosate is a systemic product, which means that once it enters the plant it gets into the circulation system and moves through the plant to the same places that the sugars are going, which are called sinks. … The sink at the pre-harvest timing is the seed. So basically what you are doing by applying early is taking what is applied to the surface of the leaf and putting it right into the seed.[11]

13. Glyphosate was first registered for use in Canada as a weed killer in 1976, prior to the 2002 enactment of the PCPA. In 1992, Agriculture Canada granted Monsanto Canada Inc.'s application to have glyphosate registered "temporarily" for a new, "pre-harvest" use on certain conventional crops.[12]

14. Over time, the permissible use of glyphosate "pre-harvest" was extended to more crops, including URMULE crops. In 2006 the PMRA permitted the "pre-harvest use" of glyphosate to be expanded to chickpeas (a URMULE crop). The PMRA granted the expansion based on a proposal submitted by Agriculture and Agri-Food Canada as sponsor, rather than from the original registrant. The basis for the expansion was deficient. In its 2006 review of this proposal for *chickpea crops*, PMRA considered and relied on glyphosate residue data it had on file from a review

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[10] **McDonald Affidavit**, at para 9, Appeal Book, Tab 6, pp 68-69.
[11] Angela Lovel, **"Don't use desiccants to hasten maturity,"** Grainews.com (4 June 2012) ("Lovel Article"), McDonald Affidavit Exhibit "L5", Appeal Book, Tab 6L, pp 442-446.
[12] Namely wheat, barley, soybeans, peas, lentils, canola and flax: **Decision Document E92-02**, Pre-Harvest Use of Glyphosate, McDonald Affidavit Exhibit "F", Appeal Book, Tab 6F, pp 194-205.

conducted in 1992 review concerning *white beans*, not chickpeas ("**1992 Review**").[13] The 1992 Review was not only dated and pertained to a *different crop entirely*, it was also of questionable reliability: in recommending an MRL for white beans in the 1992 Review, Health Canada "ignored" three white beans samples that contained materially higher residue levels because those samples had "high moisture" content and glyphosate had been applied when the plants were not fully mature.[14] Physiological maturity and moisture content are important determining variables for residue levels, so a review that discards data based on these variables is inherently unreliable.

15. To date the PMRA has not identified *any* scientific studies on the application of glyphosate to chickpea plants specifically. It has always relied on the 1992 Review relating to white beans as a proxy for the glyphosate residue levels for chickpeas and other dry beans. This is problematic because of differences in the nature of chickpea plants as compared with some dry beans and white beans. Chickpeas are "indeterminate" plants, which means they are always producing new seeds or peas. In contrast, with "determinate" plants, like some other dry beans, the production of seeds throughout the plant terminates at approximately the same time. Because indeterminate plants are always producing seeds, with some parts of the plant mature while others are immature, they are more susceptible to translocation as the glyphosate travels to the growing areas, regardless of when it is applied.

16. Pesticide registrations must be re-evaluated on a cyclical basis. Section 16(2)(b) of the PCPA required the Minister to initiate the re-evaluation of glyphosate no later than April 1, 2005. However, a 2006 internal email of PMRA shows the re-evaluation was postponed past 2005, "probably for several years."[15] In 2010, Health Canada published a work plan for the re-evaluation of glyphosate and its registrations. On April 13 2015, pursuant to s. 28(2) of the PCPA, the PMRA issued its proposed re-evaluation decision on glyphosate ("**PRVD**").[16] The PRVD included a section on risk assessment. The PMR then invited comments from the public on the PRVD before it

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[13] **URMULE D.3.2 Review**, April 24, 2006, pp 7-9, McDonald Affidavit Exhibit "W", Appeal Book, Tab 6W, pp 932-934.
[14] In the 1992 Review PMRA stated "it is assumed that white bean data (excluding the "high moisture" samples) was used to support the registration on "dry beans….". The "high moisture" samples were 3 samples with elevated residue levels, about which the reviewer did not have specific grain moisture information: **1992 Minor Use Review**, p 3 Filed Under Seal.
[15] **URMULE D.3.2 Review**, p 15, McDonald Affidavit Exhibit "W", Appeal Book, Tab 6W, p 940.
[16] **PRVD**, Certified Tribunal Record ("CTR"), Tab 41, Appeal Book, Tab 29, pp 2142-2471.

reached a final decision.[17] On April 28, 2017, the PMRA issued its re-evaluation decision ("**RVD**"). The decision (made 41 years after the initial registration of glyphosate in Canada and 12 years after the re-evaluation was to be initiated) was to continue the registration of products containing glyphosate for sale and use in Canada. The evaluation made in RVD stated:

> [A]n evaluation of available scientific information found that products containing glyphosate do not present risks of concern to human health or the environment **when used according to the revised label directions**.[18] As a requirement for the continued registration of glyphosate uses, new risk reduction measure are required for the end-use products registered in Canada. No additional data are being requested at this time.[19]

17. Subsection 35(1) of the PCPA allows "any person" to file a notice of objection to a registration decision in the form and manner directed by the Minister of Health within 60 days after the decision is made public. Eight individuals or groups filed notices of objection in respect of the RVD for glyphosate. These included the Appellant, Safe Food Matters, and its president, Mary Lou McDonald, in her personal capacity (together, the "**Objectors**"). The Objectors filed their notice of objection ("**NOO**") on June 27, 2017. Safe Food Matters Inc. is a non-profit corporation dedicated to promoting health and protecting the environment through education, awareness and engagement of Canadians on the safety of food production technologies.[20] Mary Lou McDonald is an individual who relies on the consumption of chickpeas as one of her main sources of protein.[21]

C. The Notice of Objection and PMRA Decision

18. The NOO raised nine objections to the RVD. It provided evidence in support of the objections from scientific studies, literature and government publications, as well as Health Canada policy documents.[22] The NOO stated that "the main basis for the

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[17] **McDonald Affidavit**, paras 17-18, Appeal Book, Tab 6, pp 71-72; **PRVD**, p 8, CTR, Tab 41, Appeal Book, Tab 29, pp 2156.
[18] The PRVD called for revised label directions, including as follows: "To reduce the effects of glyphosate in the environment, mitigation in the form of precautionary label statements and spray buffer zones are required. Environmental mitigation statements are listed in Appendix XII. [p 237]" **PRVD**, CTR, Tab 41, Appeal Book, Tab 29, pp 2198, 2385-2387. However, neither the PRVD nor the RVD provided a justification for those amendments.
[19] **RVD**, p 2, CTR, Tab 43, Appeal Book, Tab 31, p 2489, emphasis added; **McDonald Affidavit**, para 20, Appeal Book, Tab 6, p 72.
[20] **McDonald Affidavit**, para 2, Appeal Book, Tab 6, p 66.
[21] **McDonald Affidavit**, para 3, Appeal Book, Tab 6, p 67.
[22] **NOO**, McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, p 370.

objection is that glyphosate applied for desiccation purposes is placing residues in the seeds to the extent that they exceed MRLs and are of concern to human health, especially considering increased consumption of the relevant foods, and that evidence of such translocation and accumulation has not been considered in the Re-evaluation…". The first four objections were, essentially, support for that main basis for objecting. The remaining five objections presented other arguments. The NOO asked the PMRA to establish a review panel to assess glyphosate in light of the objections and context presented in the NOO.

19. The PMRA rejected the NOO (the "**Decision**") in a letter dated January 11, 2019, from the Chief Registrar of the PMRA (the "**Decision Letter**"). The Decision Letter stated that the NOO, "including the scientific rationale", had been assessed by a PMRA team, which "provided recommendations as to the requirement for a review panel based **on the validity and the scientific plausibility** of the issues raised in the notice".[23] The Decision Letter then recited the two factors the PMRA must consider in determining whether to establish a review panel, as set out in s. 3 of the Review Panel Regulations[24] under the PCPA (the "**RP Regulations**"), which address certain aspects of the review panel process created under s. 35(1) of the PCPA. Section 3 of the RP Regulations states:

> The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:
>
> (a) whether the information in the notice of objection raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
>
> (b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

20. The Decision Letter stated in conclusory fashion that the information submitted in the NOO does not meet either of factor.[25] An attachment to the Decision Letter set out the PMRA's responses to the objections, which it characterised as "comments".

21. As mentioned above, the NOO advanced three main rationales of the objection

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[23] **PMRA Decision Letter**, January 11, 2019, Appeal Book, Tab 4, pp 54-61.
[24] SOR/2008-22.
[25] **PMRA Decision Letter**, January 11, 2019, Appeal Book, Tab 4, pp 54-61.

to the RVD, which were supported by four specific objections. The rationales are that the evaluation did not examine one way that glyphosate gets into food, namely translocation (Objections 1 and 2); that Canadians may be exposed to glyphosate in food at levels greater than those considered in the evaluation (Objection 3); and that the measures proposed by PMRA to mitigate the risks will not work in all cases (Objection 5). In particular:

(a) **Objection 1** showed that glyphosate sprayed for desiccation purposes moves into beans and seeds of food crops by the mechanism of "translocation"; that glyphosate residue levels on plants are higher the less mature the plant is at the time of spraying; that high residue levels have been found in cereals and legumes; and that MRLs are being exceeded;[26]

(b) **Objection 2** was that when the PMRA conducted the re-evaluation it did not conduct a dietary exposure assessment on crops that have been desiccated with glyphosate or assess the associated risk;[27]

(c) **Objection 3** was that the consumption data used by PMRA is inadequate because it is outdated (from 1998), based on US diets, and does not account for the significant increase in recent years of the consumption of pulses (like chickpeas);[28] and

(d) **Objection 5** was that the risk associated with desiccation cannot be mitigated by the labels proposed by PMRA—which require that glyphosate be applied when crops are at 30% seed moisture content or less—because some crops (indeterminate) will always have some seeds with a high moisture content, and that other variables affect moisture content (like weather, and subjective determination).[29]

22. The NOO raised three objections, **Objections 6, 7 and 8**, that the PMRA did not even mention in its Response. These three objections provided rationales and evidence for the Objectors' misgivings concerning the PMRA's reliance on labels as a panacea for the otherwise unacceptable risks of glyphosate. **Objection 4** was that when setting MRLs for URMULE crops, the Minster was required to look at only the health risks. Finally, **Objection 9** noted that that the PMRA had reduced safety factors for glyphosate without valid rationale. The PMRA dismissed all of these objections.

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[26] **NOO**, McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, pp 370-372.
[27] **NOO**, McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, pp 372-373.
[28] **NOO**, McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, pp 373-377.
[29] **NOO**, McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, p 379.

D. Decision of the Federal Court

23. The Federal Court dismissed the application for judicial review. The Application Judge found that the reasonableness standard applied but in applying that test, she provided her own interpretation of the phrase "scientifically founded doubt" in s. 3(a) of the RP Regulations. According to the Application Judge's interpretation, in order to raise scientifically founded doubt the NOO must show a "well founded scientific doubt about a conclusion in the Evaluations", and that doubt must be "demonstrated by at least one controlled peer reviewed study published in a reputable journal that contradicts or raises a reasonable doubt about the Evaluations."[30] The Application Judge was "not prepared to find that a scientifically founded doubt can arise… because there is an absence of studies on a topic."[31] The Application Judge then conduct her own analysis on the objections and on whether the NOO raised a "scientifically founded doubt" according to her own interpretation, rather than reviewing the PMRA's decision to determine whether it is reasonable.

PART III - STATEMENT OF POINTS IN ISSUE

24. The issue in this appeal is whether the Application Judge correctly applied the reasonableness standard of review to the PMRA's Decision. The Appellant submits that the Application Judge erred in applying the reasonableness standard of review, and that the PMRA's Decision was unreasonable for the following reasons, which will be dealt with in turn:

(a) The Decision was not reasonable have regarding to the relevant factual and legal constrains on the PMRA's exercise of discretion including: the statutory scheme, the principles of statutory interpretation, the importance of the decision, and the submissions and evidence; and

(b) The PMRA failed to justify its Decision through reasons that explain the Decision in light of the statutory provisions and the relevant constraints.

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[30] **Federal Court Judgment and Reasons**, para 19, Appeal Book, Tab 2, p 22.
[31] **Federal Court Judgment and Reasons**, para 19, Appeal Book, Tab 2, p 22.

PART IV - STATEMENT OF SUBMISSIONS

A. Standard of review

25. In an appeal from a Federal Court decision on a judicial review application, this Court must determine whether the application judge correctly identified the appropriate standard of review and applied it correctly. To do that, this Court must step into the shoes of the court below and, in effect, re-conduct the judicial review analysis.[32] Accordingly, this appeal must focus on the administrative decision.[33]

26. The Appellant accepts that the Federal Court correctly determined that the PMRA's Decision is subject to the reasonableness standard of review. However, on a proper application of the principles set out in *Vavilov v Canada (Minister of Citizenship and Immigration)*,[34] the PMRA's Decision was unreasonable. The application judge erred in failing to reach that conclusion.

27. In *Vavilov*, the Supreme Court majority outlined the proper approach to reasonableness review. It doing so, it stressed the importance of *justification* in administrative decision-making. Where, as here, reasons have been provided, the focus must be on those reasons and not just the result. As the majority stated, "it is not enough for the outcome to be *justifiable* … the decision must be *justified*, by way of those reasons, by the decision maker to those to whom the decision applies."[35]

28. The reviewing court must pay close attention to the decision maker's reasons to ensure that the decision is the result of an "internally coherent and rational chain of analysis". The court must also assess the reasonableness of the decision in terms of the legal and factual constraints on the decision maker's discretion.[36] Significantly for this appeal, the focus must remain on the decision maker's own reasons and the reviewing court must not "fashion its own reasons in order to buttress the administrative decision."[37]

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[32] ***Merck Frosst Canada Ltd. v. Canada (Health),*** 2012 SCC 3, at ¶247, Appellant's BoA, Tab 2.
[33] ***Agraira v Canada (Public Safety and Emergency Preparedness)***, 2013 SCC 36, [2013] 2 SCR 559, at ¶¶45-47, Appellant's BoA, Tab 3; ***Farrier v Canada (Attorney General)***, 2020 FCA 25, at ¶3, Appellant's BoA, Tab 4; ***Canada (Attorney General) v Zalys***, 2020 FCA 81, at ¶54 (per Gleason JA, dissenting but not on this point), Appellant's BoA, Tab 5.
[34] ***Vavilov***, 2019 SCC 65, Appellant's BoA, Tab 1.
[35] ***Vavilov***, 2019 SCC 65, at ¶86, Appellant's BoA, Tab 1.
[36] ***Vavilov***, 2019 SCC 65, at ¶99, Appellant's BoA, Tab 1.
[37] ***Vavilov***, 2019 SCC 65, at ¶96, Appellant's BoA, Tab 1.

29. In *Entertainment Software Assoc v Society of Composers*, Justice Stratas synthesized *Vavilov* and this Court's recent case law and identified various categories of contextual factors that act constrain or liberate decision-makers. The following factors are particularly relevant in this appeal:

> (a) administrative decision-makers that are constrained by specifically worded statutory provisions or settled decisions of the courts may find their decisions set aside if they ignore these constraints;[38]
>
> (b) specific methodologies and strict language set out in statutes can be like recipes that must be followed. They can constrain and, if they are not respected, reversal can result;[39] and
>
> (c) decisions of great significance to the individual call for administrative decision-makers to supply more justification and explanation.[40]

30. In this case, and as will be explained below, the PMRA's Decision fails to meet the requisite standard of justification, transparency and intelligibility. The PMRA's discretion was constrained by the statutory scheme, the principles of statutory interpretation, importance of the decision to those affected, and the evidence and submissions before the decision maker. The PMRA's Decision was not justified in light of those constraints and therefore was not reasonable. The Application Judge failed to consider the impact of the relevant constraints on the PMRA's discretion and failed to review the Decision for an "internally coherent and rational chain of analysis". Both failures will be discussed below. She instead engaged in her own statutory interpretation, conducted her own analysis, and arrived at her own reasons to support the PMRA's outcome. This was not the approach mandated by *Vavilov*.

B. The discretion of the PMRA was constrained

31. Although the PMRA has discretion under s. 35(3) of the Act to establish or not establish a review panel after receiving a notice of objection, the reasonable exercise of that discretion was strictly constrained in this case by the governing statutory scheme of the PMRA, the principles of statutory interpretation, the importance to individual Canadian of the concerns raised in the NOO, and the evidence and submissions made in the NOO. Each will be addressed in turn.

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[38] ***Entertainment Software Assoc v Society of Composers***, 2020 FCA 100, at ¶33, Appellant's BoA, Tab 6.
[39] ***Entertainment Software Assoc v Society of Composers***, 2020 FCA 100, at ¶35, Appellant's BoA, Tab 6.
[40] ***Entertainment Software Assoc v Society of Composers***, 2020 FCA 100, at ¶36, Appellant's BoA, Tab 6.

i. Constraint 1: The governing statutory scheme

32. The statutory scheme constrained the PMRA's options in dealing with the NOO. The Decision involved an exercise of discretionary Ministerial authority. Even where an official has discretion in making a particular decision, discretion is not untrammeled. The exercise of discretion must comply with the rationale and purview of the statutory scheme.[41] The PCPA is public protection legislation. Its rationale is protection of individuals and the environment, and it seeks to achieve this protection by mandating a scientifically-based approach to the evaluation of risks, by requiring periodic re-evaluations of registered PCPs, by inviting public participation in the regulatory scheme, and by embodying a precautionary approach.

a. The PCPA's public protection objective is a broad constraint

33. The PCPA recognises that it is a matter of "national interest" to have a regulatory system the "primary objective" of which is to prevent unacceptable risks to Canadians posed by pest management control products.[42] Subsection 4(1) requires that the Minister observe this objective. It provides: "In administering the act, the Minister's primary objective is to prevent unacceptable risks to individuals and the environment from the use of pest control products". The PCPA places absolute priority on health and environmental protection.[43]

34. The PCPA emphasizes protecting the public by preventing *unacceptable risks* because PCPs are inherently harmful, a fact recognised in the preamble to the PCPA: "the availability and use of pest control products pose potential risks, both directly and indirectly, to the health, safety and well-being of individuals in Canada and to the environment."[44] The legislation prohibits the registration for use in Canada of any PCP that may pose an "unacceptable risk" to health or the environment. Subsection 2(2) describes "acceptable risk" as follows:

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[41] ***Vavilov***, 2019 SCC 65, at ¶108 citing ***Catalyst Paper Corp v North Cowichan (District)***, 2012 SCC 2, at ¶¶15, 25-28, Appellant's BoA, Tabs 1, 7; ***Roncarelli v Duplessis***, [1959] SCR 121, at 140, Appellant's BoA, Tab 8; ***Congrégation des témoins de Jéhovah de St-Jérôme-Lafontaine v Lafontaine (Village)***, 2004 SCC 48, at ¶7, Appellant's BoA, Tab 9; ***Montréal (City) v Montreal Port Authority***, 2010 SCC 14, at ¶¶32-33, and other cases, Appellant's BoA, Tab 10.

[42] **PCPA**, preamble.

[43] **Committee Report No. 1 - ENVI (36-2) - House of Commons of Canada** ("Committee Report"), Executive Summary, https://www.ourcommons.ca/DocumentViewer/en/36-2/ENVI/report-1/page-18, Appellant's BoA, Tab 15; **Government Response to the Committee Report**, p 3, Appellant's BoA, Tab 19.

[44] **PCPA**, preamble.

> 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 [emphasis added].

35. The public protection purpose is reflected in three main pillars of the PCPA: (1) a scientifically-based approach, (2) a strong re-evaluation process to ensure risks of registered products remain acceptable, and (3) public participation.

36. The first pillar requires the Minister to follow a "scientifically-based approach" when evaluating the health and environmental risks of a PCP and in determining whether those risks are acceptable.[45] A decision to register (or to continue registration of) a PCP must be based on rigorous science. For instance, under the *Pest Control Products Regulation*,[46] the party applying for registration must provide the Minister with any information that the Minister may require to evaluate the health and environmental risks and the value of the PCP, including, if relevant, the results of scientific investigations, laboratory studies and field trials respecting any of nineteen listed topics. Under s. 7(4) of the PCPA, the Minister may request the applicant to provide additional information, and has the authority to deny the application if the information is not provided. The applicant at all times bears the onus of showing that the risks associated with the PCP are acceptable.[47]

37. As the second pillar, the scheme of the PCPA requires that the risks associated with a registered PCP remain acceptable even post-registration. It mandates that a re-evaluation of each registered PCP be initiated every 15 years to ensure that registrations are supported by up-to-date science and current scientific approaches.[48] A re-evaluation decision must follow the same scientifically-based approach as initial registration decisions. The registrant maintains the onus of showing "reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product" and must provide all required information or risk de-registration. This pillar is particularly important in the instant

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[45] **PCPA**, ss 7(7), 11(2), 19(2). See also **House of Commons Debates**, 37th Parl, 1st Sess, No 204, (June 12, 2002) at 1700 (Parliamentary Secretary to Hon. Anne McLellan), Appellant's BoA, Tab 14.
[46] SOR/2006-124.
[47] **PCPA**, s. 7(6)(a).
[48] **Committee Report,** Chapters 8 and 10, pp 144, 237, https://www.ourcommons.ca/DocumentViewer/en/36-2/ENVI/report-1/, Appellant's BoA, Tab 15.

case, because glyphosate had not been re-evaluated for 41 years.

38. The third pillar of the statutory scheme is public participation. The PCPA invites public participation in the regulatory process to further the statute's objects This public participation pillar is recognised as an "ancillary objective" in s. 4(2)[49] and also in the preamble, which states:

> WHEREAS it is in the national interest that …
>
> … those persons whose interests and concerns are affected by the federal regulatory system be accorded a reasonable opportunity to **participate in the regulatory system in ways that are consistent with the attainment of its objectives…**

39. The statutory scheme reflects the public participation pillar in several places. Members of the public are consulted on registration decisions (s. 28); they may provide objections to registration decisions (s. 35); they can provide new information about a PCP and ask for a special review (s. 16(1)); and the public is to be consulted on policies, guidelines and codes of practise (s. 42.1). The notice of objection process is the only public participation mechanism in the PCPA that involves examining the quality of risk assessments underlying re-evaluation decisions.

40. The public protection purpose of the PCPA is also captured in the precautionary approach of the regulatory scheme. The precautionary principle is expressly codified in the context of decisions following a re-evaluation or special review under s. 20(1) of the Act,[50] but for initial registration decisions the legislative intent is for an even higher standard to apply.[51]

41. All decision-making of the PMRA and the Minister under the Act must comply

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[49] **Subsection 4(2)** provides: "Consistent with, and in furtherance of, the primary objective, the Minister shall …(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".

[50] **Subsection 20(1)** provides: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation."

[51] At a Senate Committee meeting when asked why the precautionary principle applied to the sections of the bill dealing with re-evaluations but not to the other sections, the Executive Director of the PMRA explained:

> [I]t is in the part of the bill dealing with re-evaluation because those products are already out in the marketplace. If there is some reason to believe there is a problem with them, we may want to be able to act quickly rather than wait until we have all of the scientific evidence. In the other part of the bill, new products do not get on the market until we are convinced that there is reasonable certainty of no harm. That is actually a more stringent endpoint than the precautionary principle.

https://sencanada.ca/en/Content/SEN/Committee/372/SOCI/03evb-e?Language=E&Parl=37&Ses=2&comm_id=47, Appellant's BoA, Tab 16.

with the rationale and purview of the statutory scheme, including the public protection purpose and the three pillars through which that purpose is achieved.

b. Specific constraints under the statutory scheme on the discretion to establish a review panel

42. In addition to the constraints imposed broadly by the statutory scheme, the Minister's exercise of discretion must also comport with the *specific constraints* imposed by the governing legislative scheme.[52] In this case, the legislature did not give the Minister a broad, open-ended discretion to establish or refuse a review panel. Rather, Parliament chose to circumscribe the discretion by making it subject to regulation. The RP Regulations limit the Minister's discretion by dictating factors that the Minister *shall* consider in arriving at a review panel decision.

43. The RP Regulations are made under, and add dimension, to the notice of objection process created under s. 35 of the Act. Once the PMRA has made a registration decision (including in respect of a re-evaluation), s. 35(1) of the Act allows "any person" to file a notice of objection. Upon receipt of a notice of objection, s. 35(3) provides that the Minister "may, in accordance with the regulations, if any, establish a panel of one or more individuals to review the decision and to recommend whether the decision should be confirmed, reversed or varied". If the Minister decides not to establish a review panel, she must provide written reasons explaining a review panel will not be established.

44. Section 2 of the RP Regulations specifies what information shall be included in a notice of objection. Section 3 sets out factors the Minister *must* consider in determining whether to establish a review panel.

45. While the language in s. 35(3) of the Act appears to afford broad discretion to the Minister to establish or refuse to establish a review panel, that discretion is constrained by s. 3 of the RP Regulations. That provision *requires* the Minister, when deciding whether to establish a review panel, to consider (a) whether the notice of objection raises scientifically founded doubt as to the validity of the evaluations the health and environmental risks of the product, and (b) whether the advice of expert scientists would assist in addressing the subject matter of the objection.

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[52] ***Vavilov***, 2019 SCC 65, at ¶108 citing ***Montreal (City) v Montreal Port Authority***, 2010 SCC 14, at ¶¶33, 40-41, Appellant's BoA, Tabs 1, 10.

46. In sum, the governing statutory scheme constrained the Minister's exercise of discretion to establish a review panel in several ways. The Decision had to: (a) accord with the primary statutory objective of preventing unacceptable risks to individuals and the environment from the use of PCPs; (b) comport with the pillars of the PCPA calling for a scientifically-based approach, strong re-evaluations, and public participation; and (c) take into account the factors set out in s. 3 of the RP Regulations.

47. As will be discussed further below, the PMRA decision refusing to establish a review panel was not reasonable in light of those constraints.

ii. Constraint 2: The principles of statutory interpretation

48. The reasonableness of the PMRA Decision was also constrained by the principles of statutory interpretation. In deciding whether to establish a review panel to consider the NOO, the PMRA had to interpret both s. 35 of the Act and the RP Regulations, especially s. 3. The PMRA's interpretation of a statutory provision had to be consistent with the text, context and purpose of the provision.[53]

49. The PMRA's Decision does not reflect an interpretation, whether implicit or explicit, that is consistent with the text, context and purpose. In fact, the Decision Letter provides no interpretation at all; it reveals *no effort whatsoever* by the PMRA to interpret the relevant statutory provisions; it merely provides a bare recitation of the factors in s. 3 of the RP Regulations. Nowhere in the Decision does the PMRA explain to the Appellant or a reviewing court how it interpreted the relevant provisions or what considerations bore on the exercise of its discretion.

50. There may be cases in which a decision maker has not explicitly considered the meaning of a relevant provision in its reasons, but the reviewing court is able to discern the interpretation adopted by the decision maker from the record and determine whether that interpretation is reasonable.[54] This is not such a case. The record reveals no analysis by the PMRA of the meaning of the relevant provisions or how the provisions had to be applied to the NOO.[55]

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[53] ***Vavilov***, 2019 SCC 65, at ¶¶117-121, Appellant's BoA, Tab 1.
[54] ***Vavilov***, 2019 SCC 65, at ¶123, Appellant's BoA, Tab 1.
[55] The record reveals no attempt to interpret the factors in either the briefings for or the minutes of the Science Management Committee meetings: **Minutes and Briefing Notes, 2017-2018**, McDonald Affidavit Exhibit P,

51. The PMRA's Decision is not consistent with the text, context and purpose of the operative provisions. The operative provisions the PMRA had to apply in this case—s. 35 of the Act and s. 3 of the RP Regulations—must be understood not only by their own text, but also in the context of the Act and its purposes, as described above. In addressing the role of statutory interpretation principles in this case, the Appellant will focus on two particular aspects of the requirement in s. 3(a) of the RP Regulations: (1) that the Minister consider whether the information in the notice of objection "raises scientifically founded doubt"; and (2) that the "doubt" relate to the "validity of the evaluations, on which the decision was based, of the health and environmental risks" of the PCP.

a. Interpretation of "raise a scientifically founded doubt"

52. Paragraph 3(a) of the RP Regulations calls on the Minister to assess whether "the information in the notice of objection **raises scientifically founded** doubt". These words set a low standard. RP Regulations do not require that the NOO "establish", "prove" or "persuade", for example. And "raising a doubt" does not indicate, despite the finding of the Application Judge, that the NOO must show a "well-founded scientific doubt about a conclusion" demonstrated by "at least one controlled peer reviewed study published in a reputable journal" or "challenge the science".[56]

53. The context of the PCPA also signals a low standard. The choice of the words "raise a doubt" in the RP Regulations contrasts with s. 7(6) of the PCPA, which puts the onus on an applicant (at the application stage) to "persuade" the Minister that the health and environmental effects and the value of the PCP are acceptable.

54. The words "raises scientifically founded doubt" should also be viewed through the lens of the legal concept of 'doubt' in other areas of Canadian law. The legal concept of 'reasonable doubt' is deeply entrenched in criminal law. In choosing to use the same word 'doubt' in s. 3(a) of the RP Regulations, the Governor in Council must be presumed to have intended a consistent meaning. As explained in Ruth Sullivan's authoritative text on the construction of statutes:

Appeal Book, Tab 6P, pp 811-853. However, meeting notes reveal efforts to craft arguments to dismiss the objections: **Glyphosate NOO meeting notes**, CTR, Tab 44, Appeal Book, Tab 32, pp 2591-2592.

[56] **Federal Court Judgment and Reasons**, paras 17, 19, Appeal Book, Tab 2, pp 21-22.

> When used in legislation, common law terms and concepts are presumed to retain their common law meaning. …
>
> For the presumption to apply it is unnecessary that the legislation exactly reproduce the common law terminology. So long as it uses language that is apt to refer to the common law principle or concept, the presumption applies.[57]

55. The choice of "*scientifically founded*" as a qualifier of "doubt" in s. 3(a) of the RP Regulations indicates an intention to modify the criminal law standard of '*reasonable* doubt'. However, there is no indication that the Governor in Council intended to change the meaning of the word 'doubt' when it used that word in the Regulations. To the contrary, it should be resumed that the word 'doubt' retains its common law meaning—but the *basis* for that doubt must be scientifically founded.

56. In *R v Lifchus,* the Supreme Court of Canada described 'reasonable doubt' in the context of the standard of proof in criminal cases according to the following characteristics: (1) reasonable doubt is logically connected to evidence or the absence of evidence; (2) it does not require proof to an absolute certainty; and (3) it is not proof beyond any doubt nor is it an imaginary or frivolous doubt.[58]

57. Drawing on the *Lifchus* definition of 'reasonable doubt' and the direction in s. 3(a) of the RP Regulations that the NOO must raise a 'doubt' that is scientifically founded, the Appellant submits that the reasonable interpretation of the words in s. 3(a) is that a "scientifically founded doubt" is logically connected to evidence or the *absence* of evidence that is scientifically founded. It is doubt that arises logically from a consideration of the evidence on a point that is scientifically founded, or the lack thereof.[59]

58. This interpretation of "scientifically founded doubt" is also consistent with the context of s. 3(a) within the RP Regulations. Section 2 of the Regulations spells out what must be included in a notice of objection, and it does not require proof to an absolute certainty or beyond a doubt. It requires that the notice of objection include:

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[57] Ruth Sullivan, ***Sullivan on the Construction of Statutes***, 6th Ed (LexisNexis Canada Inc.) §17.14, Appellant's BoA, Tab 17. See also ***R v Holmes***, [1988] 1 SCR 914 at 929-930, Appellant's BoA, Tab 11.
[58] ***R v Lifchus***, [1997] 3 SCR 320 at ¶36, Appellant's BoA, Tab 12.
[59] **National Judicial Institute**, *Model Jury Instructions*, section 5.1, https://www.nji-inm.ca/index.cfm/publications/model-jury-instructions/preliminary-instructions/fundamental-principles/presumption-of-innocence-burden-of-proof-and-reasonable-doubt/, Appellant's BoA, Tab 18.

> (a) the *scientific basis* for the objection to the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product; and
>
> (b) *the evidence* to support the objection, including scientific reports or test data.

59. The need for a "scientific basis" for the objection asks for a rationale or a line of reasoning—a theory—that is based in science.[60] The rationale must be accompanied by supporting evidence, as set out in s. 2(d)—which *may include* scientific reports or data, but is left open-ended.

60. With respect to purpose, s. 3(a) allows for members of the public to raise objections as a "check" on the decision-making and analysis conducted by PMRA in its risk assessment. That is exactly what the Objectors did in this case through the NOO. This purpose is supported by the fact that the notice of objection process is the only public participation mechanism in the PCPA that examines re-evaluations.

61. The above interpretation of raising a "scientifically founded doubt" as to the validity of an evaluation is also consistent with the public protection purpose of the PCPA and the associated requirement that the Minister may consider the risks of a PCP to be "acceptable" only if there is a "reasonable certainty" that the PCP will cause no harm to human health, future generations or the environment.

62. If a NOO raises a "doubt" that is logically connected to scientifically founded evidence (or the absence of such evidence) regarding the validity of the evaluations of risks, then the Minister cannot be reasonably certain that the PCP will cause "no harm". In such a case it is appropriate for the Minister to exercise her discretion to establish a review panel to investigate the concern. Once a scientifically founded doubt has been raised, the consideration and advice of a review panel will often be necessary before there can be reasonable certainty of no harm.[61]

63. The foregoing interpretation also supports the public participation objective of the PCPA. If too high a bar were set for raising "scientifically founded doubt", it

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[60] This concept of a "rationale" with evidence to support runs throughout PMRA statements. For example, "scientific rationale" is mentioned in the first page of the **Decision Letter**, Appeal Book, Tab 4, p 54.

[61] See also ***Wier v Canada (Health)***, 2011 FC 1322, at ¶¶97-98, albeit in respect of s. 17(1) of the PCPA, which imposes a threshold of "reasonable grounds to believe", which is higher than "scientifically founded doubt": Appellant's BoA, Tab 13.

would frustrated the public participation object since members of the public do not have the resources to conduct or commission scientific studies. This interpretation is also consistent with the precautionary principle codified in the PCPA.

64. The PMRA failed to adopt or apply the above interpretation of "scientifically founded doubt" or *any other* interpretation of that phrase, and the substance of the Decision was not justified by any reasonable interpretation of the statutory wording.

65. The Application Judge fell into error by not assessing whether the PMRA had reasonably interpreted the words "raises a scientifically founded doubt". She compounded that error by arriving at her own interpretation, which buttressed the PMRA's conclusion but did not reflect the text, context and purpose of the legislation. The Application Judge equated "raise a scientifically founded doubt" to "contradict a conclusion" or "challenge the science". She also held that such doubt must be based on "at least one controlled peer reviewed study published in a reputable journal". Respectfully, those interpretations (which are not derived from the PMRA's Decision) are not supported anywhere by the text, context or purpose of s. 3 of the RP Regulations, or the PCPA or its purpose.

b. Interpretation of "validity of the evaluations … of the health and environmental risks"

66. Beyond the words "scientifically founded doubt", the PMRA offered no interpretation of the other pertinent part of s. 3(a): that the doubt be raised as to the "validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pest control product".

67. The text and plain wording of s. 3(a) the RP Regulations are clear that the focus of the doubt is on the "validity" of the evaluations. The words "validity of the evaluations" may be capable of a range of meanings. The Appellant accepts that a "valid" evaluation could be informed by the institutional setting and context of a PMRA decision. However, as with "scientifically founded doubt", the PMRA offered no interpretation, explanation or insight in the Decision into how it understood and applied that concept to the NOO. The PMRA simply provided explanations that countered or explained away the points raised, or ignored them altogether, without considering whether or how those objections might raise doubt about *the validity of the*

evaluations of health risks. Significantly, PMRA stated in the Decision Letter that the requirement for a review panel was "based on the validity and scientific plausibility of the **issues raised** in the [NOO]". From that statement it appears the PMRA's focus was, at best,[62] on the "issues raised" in the NOO, and not—as it should have been according to s. 3(a)—on whether or how those issues impacted the validity of the evaluations.

68. Had the PMRA turned its mind to what s. 3(a) required, it would have appreciated that the statutory scheme is very clear about what are the relevant "evaluations" for the purpose of s. 3(a) of the RP Regulations. The relevant "evaluations" are the "reports of the evaluation of the health and environmental risks and the value" that form part of a "consultation statement", as described in s. 28 of the PCPA. The scheme operates as follows:

(a) Under s. 28(1) the Minister must consult the public (and government agencies) before making a continued registration decision following a re-evaluation.

(b) The Minister initiates the consultation by publishing a "consultation statement" and inviting written comments (s. 28(2)).

(c) Section 28(3) sets out the content of the required consultation statement:

> **Consultation statement**
>
> 28(3) The consultation statement shall include
>
> (a) a summary of any **reports of the evaluation of the health and environmental risks** and the value of the pest control product prepared or considered by the Minister;
>
> (b) the proposed decision and the reasons for it; and
>
> (c) any other information that the Minister considers necessary in the public interest.

(d) Subsection 28(4) requires the Minister to consider comments received in the consultation before making a decision.

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[62] With respect to the NOO, it appears the focus of the PMRA's Science Committee was not even on issues. The NOO's objections were presented in a table in Appendix 1 to the briefing note for the July 6, 2017 meeting in the form of summary phrases (1 to 5 words) that were not specific to the objections actually made. The evidence was not presented: **Briefing Note**, July 6, 2017, McDonald Affidavit Exhibit P, Appeal Book, Tab 6P, pp 824-832.

(e) Subsection 3(a) of the RP Regulations calls for the Minister to consider whether a notice of objection raises scientifically founded doubt about the validity of the evaluation of the health and environmental risks and the value of the PCP as disclosed in the consultation statement.

69. In this case, the PRVD is the "consultation statement" under s. 28(3). It contains a section entitled "Science Evaluation", which constitutes the "reports of the evaluation of the health and environmental risks". Applying the presumption of consistent expression,[63] the reference to "evaluations, on which the decision was based, of the health and environmental risks … the pest control product" in s. 3(a) of the RP Regulations should be understood to be the same "evaluation of the health and environmental risks" referred to in s. 28(3) of the PCPA.

70. The link between "evaluation" in s. 28(3) of the PCPA and "evaluation" in s. 3(a) of the RP Regulations is supported by the PMRA's own guidance documents. The PMRA's process for evaluating the risks and value of a PCP is set out in a publication entitled *Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks* (the "**Framework**"). The Framework consists of a series of interconnected and interrelated steps for decision-making, comprised of issue identification, risk assessment and risk management.[64] The second step, "risk assessment", maps onto the evaluation of risks that is the subject of s. 3(a) of the RP Regulations and that was detailed in the Science Evaluation section of the PRVD.

71. According to the Framework, the goal of a risk assessment is to estimate the level of harm posed by a substance (the "hazard") and the levels of exposure to that harm (the "exposure"), to make an assessment of whether there are risks of concern. A risk assessment follows a four step *process* that is internationally recognized.[65] The first two of the four steps ("hazard identification" and "hazard characterization") are concerned with identifying the hazard, the third ("exposure assessment") is concerned with determining the exposure, and the fourth ("risk characterization") is the

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[63] Ruth Sullivan, ***Sullivan on the Construction of Statutes***, 6th Ed (LexisNexis Canada Inc.) §§8.32-8.35, Appellant's BoA, Tab 17.
[64] **Framework**, p 10, McDonald Affidavit Exhibit "A", Appeal Book, Tab 6A, p 96.
[65] **SPN2000-01 Technical Paper**, p. 6, McDonald Affidavit Exhibit "B", Appeal Book, Tab 6B, p 151. The Framework describes the steps as: (1) hazard identification (is it harmful?); (2) hazard characterization (how harmful is it?); (3) exposure assessment (what levels are humans exposed to); and then (4) risk characterization (a summary and integration of the scientific analysis from the preceding tasks). The steps are summarised in the **Framework**, p 27, McDonald Affidavit Exhibit "A", Appeal Book, Tab 6A, p 113.

assessment itself, based on the previous steps.

72. Part of the first step is "identifying the mode and mechanism of action of the agent",[66] and part of the third step is determining how much of the agent a population or subpopulation is exposed to through various exposure pathways, including through their food.[67] The Framework emphasizes "it is important to include ***all relevant scientific data*** in the assessment of health risks".[68]

73. The focus in s. 3(a) of the Regulations is on the validity "*of the evaluations, on which the decision was based*", rather than on the decision itself.[69] Because the evaluations are comprised of a four step process, the focus of the inquiry must be on the analysis set out in the PRVD for each of the four steps of the risk assessment *process*—not on just the last step, the *outcome* or conclusion of the process, which was the focus of the Application Judge.

74. The regulatory scheme focuses on the *process* for a risk assessment because a sound process engenders confidence in the outcome. Conversely, a conclusion based on a flawed process cannot be considered a valid conclusion leading to a "reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product". An emphasis on process emphasis thus supports the public protection purposes of the PCPA.

75. The Framework notes the following as requirements of risk characterization:

- ***Get the science right:*** Ensure that the underlying analysis meets high scientific standards in terms of measurement, analytic methods, databases used, plausibility of assumptions, and consideration of both the magnitude and the nature or uncertainty, taking into account limitations that may result from the level of effort expanded on the analysis.
- ***Get the right science:*** Ensure that the analysis addresses the significant risk-related concerns of public officials and the spectrum of interested and affected parties. Set priorities for assessment so as to emphasize the issues most relevant to the decision.[70]

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[66] **Framework**, p 29, McDonald Affidavit Exhibit "A", Appeal Book, Tab 6A, p 115.
[67] **Framework**, pp 30, 31, McDonald Affidavit Exhibit "A", Appeal Book, Tab 6A, pp 116-117.
[68] **Framework**, p 27, McDonald Affidavit Exhibit "A", Appeal Book, Tab 6A, p 113. Emphasis added.
[69] This interpretation is consistent with the distinction in s. 28(3) of the PCPA between the "reports of the evaluation of the health and environmental risks" in 28(3)(a) and the "proposed decision" in 28(3)(b).
[70] **Framework**, p 33, McDonald Affidavit Exhibit "A", Appeal Book, Tab 6A, p 120.

76. Given that the PMRA did not provide any interpretation in the Decision on the meaning of "validity of the evaluations", the Appellant encourages the Court to recognise that the PCPA and the Framework call for the following interpretation: In order to raise doubt as to the "validity of the evaluations" of risk on which a registration decision was based, a NOO must point to concerns with measurement, analytic methods, databases used, plausibility of assumptions and/or the treatment of uncertainty in any of the steps in the process, or show that all relevant current scientific data was not included in the assessment of health risks. In other words, raise a doubt that PMRA "got the science right" or "got the right science".

iii. Constraint 3: The impact on individuals

77. *Vavilov* requires that "where the impact of a decision on an individual's rights and interests is severe, the reasons provided to that individual must reflect the stakes."[71] A decision to continue a PCP registration where there is scientifically founded doubt surrounding the validity of the risk assessments relating to that PCP could have serious health consequences. The decision affects the interest of Ms. McDonald in obtaining uncontaminated, safe protein sources in her diet. The Decision has great significant for her health.

78. Further, since a decision that affects the life, liberty or dignity of one individual "must reflect the stakes", *a fortiori* that must apply where a decision has the potential to affect the health of millions of Canadians as is the case with the PMRA's decision to continue the registration of glyphosate. The PRMA's refusal to establish a review panel in the face of the serious concerns raised in the NOO impacts not only the Appellant and Ms. McDonald, but all Canadians. The PMRA failed to grapple with those consequences or to "explain why its decision best reflects the legislature's intention".[72] The culture of justification demanded much more from the PMRA for its decision to pass muster on reasonableness review.

iv. Constraint 4: The evidence and submissions

79. Finally, the PMRA's decision was constrained by the facts and submissions before it, which raised scientifically founded doubt as to the validity of the evaluations

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[71] ***Vavilov***, 2019 SCC 65, at ¶133, Appellant's BoA, Tab 1.
[72] ***Vavilov***, 2019 SCC 65, at ¶133, Appellant's BoA, Tab 1.

of the health risks on which the RVD was based.[73] The submissions and evidence in the NOO revolved around three main arguments: (1) that due to translocation to seeds, high levels of glyphosate accumulate in seeds of certain desiccated plants that are not mature, and the associated risks were not considered in the risk assessment; (2) that accurate, relevant consumption data was not used in the assessment of dietary exposure; and (3) that indeterminate crops will always attract high levels of glyphosate in their seeds, which means that there will always be an unacceptable risk with these crops that cannot be mitigated by labels.

a. Submissions regarding translocation, high residue levels and the determining variable of physiological maturity

80. The PRMA did not meaningfully grapple with the submissions set out in Objection 1 of the NOO. The Decision did not address the concern that when glyphosate is applied to crops pre-harvest, it translocates to the seeds. Nor did it respond to the "physiological maturity" point that residues levels in the seed will be higher if desiccation occurs before the plant is physiologically mature. The NOO made these points alongside a body of supporting scientific literature and data.[74]

81. The PMRA fundamentally misapprehended the evidence presented in Objection 1. The PMRA stated that it had assessed the scientific literature cited in support of Objection 1 and that "the cited references show that residues of glyphosate increase when applied as a preharvest treatment when the moisture content of the crop is more than 30%."[75] It then indicated there is no concern because labels require application at less than 30% moisture content.

82. However, the articles referenced in Objection 1 did *not* show that residues increase when applied at more than 30% crop moisture content. Where the studies speak to moisture at all, they speak to *seed* moisture content, not *crop* moisture content. And only three of them[76] used seed moisture content as the sole variable for

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[73] ***Vavilov***, 2019 SCC 65, at ¶¶125-128, Appellant's BoA, Tab 1.
[74] **NOO**, McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, pp 370-372 and supporting articles cited therein which are at Appeal Book, Tabs 6L2-6L3, 6L5, 6L7, 6L8, 6L9, 6L12, 6L13, 35.
[75] The Respondent's affidavit, Isabelle Pilote, also focusses exclusively on moisture content in her affidavit: **Affidavit of Isabelle Pilote**, affirmed June 27, 2019, ¶37 Appeal Book, Tab 8, p 1018.
[76] Only three of them (the **Zhang studies** at Tabs 6L8, 6L9 and 6L12 of the Appeal Book all relating to red lentils) used seed moisture content as the sole variable for determining residues. Three studies by **Cessna *et al*** (at Tabs 6L2, 6L3 and 35 of the Appeal Book) examined "stage of crop development" (i.e. physiological maturity) and although seed moisture content was an indicium of stage of development, it was combined with a second indicium,

determining residues. In one study,[77] moisture content was *not even a variable*; the variable was "maturity" and it was based on the percentage of pods changing colour. Some of the studies explain the relationship between physiological maturity and moisture content, and others point out the problems with using seed moisture content as a determining variable. For instance, the authors of one study state:

> Several factors can influence the magnitude of residues in/on the seed of wheat which has received preharvest application of glyphosate. The physiological stage of the crops at the time of glyphosate application is one of the most important. **The more physiologically mature the crop, the lower its moisture content and the lower the chance of uptake and translocation to the seed**.[78]

83. PMRA's misunderstanding of Objection 1 and the underlying evidence led it to focus on only ONE of the two variables raised in the NOO (moisture content), and, in turn, to respond that the labels are a complete answer for the relevant variable. However, labels are not a solution to the risk of high levels, because they speak to moisture content *only*, not to physiological maturity.[79] The glyphosate labels state that spraying should occur when the crop has 30% or less grain moisture content, and then provides visual indicators "for this stage in each crop".[80] The labels are clear that visual indicators are provided to assist in determining when a seed has reached the stage of 30% moisture content; they do not indicate that these visual indicators also reflect the appropriate stage of physiological maturity. As such, they might address the risk of high levels associated with spraying glyphosate on crops with more than 30% seed moisture content, but do not address the risk of high levels associated with

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seed condition, in one of the studies (the 2002 study on field pea, barley and flax at Tab 6L3 of the Appeal Book). In another study (the 2000 study on canola) it was concluded that "seed moisture content was not a reliable indicator" of stage and "should not be the only criterion used": p 427, Appeal Book, Tab 6L2, p 401.

[77] **McNaughton *et al,*** "Effect of application timing of glyphosate and saflufenacil as desiccants in dry edible bean," McDonald Affidavit Exhibit L7, Appeal Book, Tab 6L7, pp 458-464.

[78] **Cessna, A.J. et al, Wheat Seed Study**, 1994, at 654, CTR, Tab 49, Appeal Book, Tab 35, p 2633. Similarly, the second **Cessna Canola Seed Study, 2000** (at 427) states: "The agronomy data also established that, **due to the dependence of seed/pod moisture content on environmental conditions, seed/pod moisture content was not a reliable indicator** of canola development and should not be the only criterion used to indicate the appropriate time for preharvest glyphosate application", McDonald Affidavit Exhibit "L2", Appeal Book, Tab 6L2, p 401. The **Cessna Field Pea, Barley and Flax Study, 2002** makes a similar point (at 489) (as part of the conclusion that the primary determinants for residues were rate of application and physiological maturity), stating: "residues of the herbicide and its metabolite were also affected by rainfall washoff and by environmental conditions that affected the moisture content of the crop", McDonald Affidavit Exhibit "L3", Appeal Book, Tab 6L3, p 412.

[79] In addition, the labels are long and complex. See, for example, **CTR**, Tab 4, Appeal Book, Tab 11, pp 1159-1258.

[80] **CTR**, Tab 4, p 79, Appeal Book, Tab 11, pp 1237.

spraying on crops that are physiologically immature.

84. Objection 1 raised scientifically founded doubt about the validity of the evaluations of risk on which the RVD was based. Translocation represents the "mode or mechanism of action" of glyphosate in a plant, and as such should have formed part of the "hazard identification" step of the risk assessment process. The fact that it was not indicates that the PRMA did not examine "all relevant scientific data" in its risk assessment process, as it ought to have. A panel of independent scientists would assist, including by investigating the mechanism of action of glyphosate, that causes it to accumulate in high levels in cereals and legumes

85. Objection 2 in the NOO submitted that the PMRA did not discuss dietary exposure from desiccated crops and did not examine the risk arising from such exposure.. The NOO called for an examination of such risks, particularly given the mechanism of translocation that had been explained already in Objection 1.

86. The PMRA did not respond to the two points, failing entirely to grapple with the issues. It stated only that the pre-harvest "use" of glyphosate had occurred in residue trials and that therefore the dietary exposure assessment had encompass pre-harvest use. However the fact that a dietary risk assessment included pre-harvest use does not mean there was an examination of either: (a) the potential for harm (high residue levels from translocation) arising from exposure to desiccated crops; or (b) the magnitude of exposure to such harm—both of which are required in a valid risk assessment, which was pointed out in the objection.

87. Objection 2 raised scientifically founded doubt about the validity of the evaluations. The PMRA did not identify the risk of potential high glyphosate residue levels due to translocation as a risk that must be assessed. This raises serious questions about the conclusion that there are "no unacceptable risks". If a risk has not been examined, it cannot be said with reasonable certainty that no harm will result from this unexamined risk. Moreover, the absence of evidence on this risk is a sign that PMRA did not "get the right science" and raised doubt about the validity of the evaluation. An independent panel could assist investigate by investigating the use of more relevant and accurate data from other databases on Canadian consumption, and also the use of up to date modelling methods for exposure.

b. Submissions regarding the indeterminate nature of plants, chickpeas, and that the unacceptable risk cannot be mitigated

88. The rationale of Objection 5 was that the risk associated with desiccation cannot be mitigated by labels that require spraying at less than 30% seed moisture content for three reasons: (1) indeterminate plants, by their nature, always have young seeds that have seed moisture of more than 30%, (2) seed moisture content is affected by weather, and (3) the determination of moisture content by visual indicators is prone to error. The NOO provided evidence supporting these points, and concluded that there is no reasonable certainty of "no harm" given these points.

89. Again, the PMRA did not grapple with the issues and central arguments raised in the submission. It did not respond at all to the points raised, particularly the central argument that indeterminate plants will always have young seeds[81] that will always attract glyphosate. Nor did the PMRA justify, in light of the NOO's arguments on these points, a conclusion that there is "no harm". It merely noted that the labels indicate when to spray.

90. The concerns relating to indeterminate plants are exacerbated in the case of chickpeas, because not only are they indeterminate and (as discussed below) there is evidence showing dietary consumption of chickpeas has increased, but also the PMRA has *never* collected *any data whatsoever* about the pre-harvest use of glyphosate on chickpea crops.[82] As noted above, the study that formed the basis for permitting pre-harvest use of glyphosate on chickpea crops was flawed. The 1992 Review is outdated and related to a different crop entirely. Most significantly, the study "ignored" three residue test samples because they had *high moisture content* and had been applied *prior to maturity*. Of course, physiological maturity and moisture content are determining variables for residue levels, and the PMRA considers residue levels to be "an essential part of ensuring that the dietary intake of pesticide does not lead to unacceptable exposure and risks to human health". By failing to even look at the 1992 review to appreciate its flaws—let alone consider the need for new data for pre-harvest use on glyphosate in chickpeas—the PMRA did not take into account the relevant

[81] As noted by the Application Judge, with indeterminate plants "even at harvest time, parts of the plant may be immature": **Federal Court Judgment and Reasons**, para 25, Appeal Book, Tab 2, p 24.
[82] The PMRA continues to rely on old, problematic data from the 1992 Review relating to a different crop (white bean) to support uses on chickpeas, without having even looked at the 1992 Minor Use Review report: **Email from G Evans (AGC counsel) to A Gonsalves**, July 11, 2019, Filed Under Seal.

evidence on the concerns relating to chickpeas.

91. Scientifically founded doubt about the validity of the evaluations was raised in Objection 5 and in the evidence—and absence of evidence—specific to the fate of glyphosate in indeterminate crops. The fact that indeterminate crops will always have moist seeds and poses a risk that cannot be mitigated by labels casts doubt as to the outcome of the evaluation that there are no risks of concern or unacceptable risks. An independent panel could assist investigate by identifying the stages of physiological maturity that are problematic, and revising the labels to account for this variable.

c. Submissions regarding dietary risk assessment

92. Objection 3 was that the dietary data used in the dietary exposure assessment was outdated, from the US, and insufficient for evaluation purposes particularly because it does not account for the significant increase in the consumption of pulses like chickpeas and lentils over time.[83]

93. In its Decision, the PMRA failed to account for the evidence concerning increased consumption of pulses.[84] It simply ignored the point. It also did not meaningfully grapple with the submission that the outdated data is insufficient for purposes of evaluating glyphosate and that accurate, current data is required. It made statements concerning "consistency" between the old data and a newer database, but did not explain why the newer data was not used or explain on what basis it found the old and new databases to be "consistent".[85] The Decision expressed the PMRA's "expectation" that the results would have been the same had updated consumption data been used, but a mere "expectation" does not support a valid evaluation and has no place in a scientifically based risk assessment.

94. The PMRA unreasonably failed to find that Objection 2 raised scientifically founded doubt about the validity of the evaluations. The *absence* of current, reliable food consumption data indicates PMRA did not obtain all "relevant scientific data" or

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[83] **NOO,** McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, pp 373-377 and references cited therein.
[84] **NOO,** McDonald Affidavit Exhibit "K", Appeal Book, Tab 6K, p 375: The consumption of chickpeas in the United States has grown at least 90% since 2010. As stated in the NOO, "hummus is a dip made form chickpeas, and over a quarter of Americans reported in 2014 that they had the dip in their refrigerators".
[85] The application judge put the onus on the Objectors to provide "dietary consumption data of the sort relied upon by the PMRA" (**Federal Court Judgment and Reasons**, ¶56, Appeal Book, Tab 2, p 33), even though the onus is on the registrant to persuade PMRA that the risk are acceptable.

"get the right science". The fact that an older model of dietary risk assessment was used in the evaluation raised concerns regarding the data bases and methodology used. It also raised concerns with the outcome that the risks are acceptable.

C. The PMRA Decision was not reasonable in light of the constraints

95. In light of the legal and factual constraints on the PMRA's discretion, the total absence in the Decision of any attempt to interpret relevant provisions, and the absence of any internally coherent and rational chain of analysis justifying the PMRA's refusal to establish a review panel, having regard to the limits on its discretion, the PMRA's Decision was not reasonable. The Decision's failings of justification, transparency and intelligibility are even more pronounced given the important to the individual of safe food consumption. The legislative regime and statutory interpretation required the PMRA to conduct a scientifically based risk assessment at the re-evaluation stage, and to consider whether the rationale and evidence provided in the NOO raised scientifically doubt about the validity of the evaluations. The importance of the re-evaluation was pronounced because glyphosate had not been looked at for 41 years.

96. In dismissing the Appellants objections, without grappling with the substance of the arguments and the evidence presented, and applying to them the standard of "scientifically founded doubt as to the validity of the evaluations" of risks, the PMRA did not show that it exercised its review panel discretion in accordance with the precautionary and public protection purpose and scheme of the PCPA. To the contrary, the Decision *undermines* the fundamental statutory objective. In dismissing the objections, the PMRA was not fulfilling the requirement of the PCPA of ensuring there is a reasonable certainty of no harm to individual Canadians arising from the risks associated with glyphosate.

PART V - STATEMENT OF ORDER SOUGHT

97. Based on the evidence before the Court and the foregoing submissions, the Appellant respectfully requests an order quashing the Decision and directing the Minister to establish a panel of one or more individuals to review the subject matter of the NOO, or in the alternative, an order remitting the matter to the Minister for reconsideration in accordance with the Court's reasons.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 4th day of December, 2020.

Andrea Gonsalves
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Lawyers for the Appellant

PART VI - LIST OF AUTHORITIES

1. *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65,
2. *Merck Frosst Canada Ltd. v. Canada (Health)*, 2012 SCC 3
3. *Agraira v Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 SCR 559
4. *Farrier v Canada (Attorney General)*, 2020 FCA 25
5. *Canada (Attorney General) v Zalys*, 2020 FCA 81
6. *Entertainment Software Assoc v Society of Composers*, 2020 FCA 100
7. *Catalyst Paper Corp v North Cowichan (District)*, 2012 SCC 2
8. *Roncarelli v Duplessis*, [1959] SCR 121
9. *Congrégation des témoins de Jéhovah de St-Jérôme-Lafontaine v Lafontaine (Village)*, 2004 SCC 48
10. *Montréal (City) v Montreal Port Authority*, 2010 SCC 14
11. *R v Holmes*, [1988] 1 SCR 914
12. *R v Lifchus*, [1997] 3 SCR 320 6
13. *Wier v Canada (Health)*, 2011 FC 1322

Secondary Sources

14. House of Commons Debates, 37th Parl, 1st Sess, No 204, (June 12, 2002)
15. House of Commons of Canada, Committee Report No. 1 - ENVI (36-2): https://www.ourcommons.ca/DocumentViewer/en/36-2/ENVI/report-1/
16. Proceedings of the Standing Senate Committee on Social Affairs, Science and Technology, Issue 3 – Evidence of November 7, 2002: https://sencanada.ca/en/Content/SEN/Committee/372/SOCI/03evb-e?Language=E&Parl=37&Ses=2&comm_id=47
17. Ruth Sullivan, *Sullivan on the Construction of Statutes*, 6th Ed (LexisNexis Canada Inc.)
18. National Judicial Institute, *Model Jury Instructions*, section 5.1: https://www.nji-inm.ca/index.cfm/publications/model-jury-instructions/preliminary-instructions/fundamental-principles/presumption-of-innocence-burden-of-proof-and-reasonable-doubt/
19. Government Response to the Committee Report

Statutes and Regulations

20. *Pest Control Products Act*, SC 2002, c 28

21. *Pest Control Products Regulation*, SOR/2006-124
22. Review Panel Regulations , SOR/2008-22