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/LES AMIS DE LA TERRE

Interveners

RESPONDENTS' MEMORANDUM OF FACT AND LAW

February 12, 2021

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I. OVERVIEW AND STATEMENT OF FACTS

A. OVERVIEW

1. The Application Judge did not err when she concluded that the Pest Management Regulatory Agency ("PMRA") reasonably determined that the Appellant's Notice of Objection ("NOO") did not provide a basis for establishing an expert panel to review PMRA's evaluations concerning the safety of glyphosate. This determination followed years of scientific review and consultation. PMRA reviewed hundreds of studies, published a detailed explanation of its proposed decision for public consultation, and issued a detailed final decision. Twenty PMRA scientists who were not involved in that decision reviewed the Appellant's NOO. They concluded that the NOO did not raise scientifically founded doubt as to the validity of PMRA's scientific evaluations and that the advice of external expert scientists would not assist PMRA in addressing the subject matter of the objections. PMRA therefore declined to exercise its statutory discretion to establish a review panel. The Application Judge correctly determined that PMRA's decision was reasonable. There is no basis for this Court's intervention.

B. STATEMENT OF FACTS

a. Legislative Framework

2. PMRA, acting on behalf of the Minister of Health, is responsible for the regulation of pesticides in Canada in accordance with the *Pest Control Products Act* ("Act") and regulations thereunder.[1]

3. The Act requires all pesticides to be registered (or otherwise authorized) for use in Canada.[2] Once registered, pesticides must have PMRA-approved labels

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[1] *Pest Control Products Act*, SC 2002, c 28 ("Act"), **Appellant's Book of Authorities ("ABA"), Tab 20**. Relevant regulations include *Pest Control Product Regulations*, SOR/2006/124 ("PCP Regulations"), **ABA, Tab 21** and *Review Panel Regulations*, SOR/2008-22 ("Panel Regulations"), **ABA, Tab 22**. Where PMRA is referenced in this factum, those references are to PMRA acting on behalf of the Minister of Health.

[2] Act, s 6, **ABA, Tab 20**

stipulating directions for proper usage.[3] The Act provides that no person may handle, store, transport, use or dispose of a registered pesticide in a way that is inconsistent with the PMRA-approved label.[4] Contravention of any of the provisions in the Act or regulations is punishable by either a criminal offence (on summary conviction or on indictment), or an administrative monetary penalty.[5]

4. Before a pesticide can be registered for use, PMRA conducts a rigorous science-based assessment of the human health impacts and environmental risks posed by that pesticide.[6] PMRA is required to register a pesticide if (and only if) it considers that the health and environmental risks and the value of the product are "acceptable" after any required consultations and evaluations have been completed.[7] The onus of establishing that risks are acceptable lies with the applicant.[8]

5. Pursuant to subsection 2(2) the risks of a pesticide 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.[9] Health risk is defined in the Act as "the possibility of harm to human health resulting from exposure to or use of the product, taking into account the conditions or proposed conditions of registration."[10] Conditions of registration are conditions specified by PMRA when approving or amending a pesticide's registration (including label instructions) and any requirements

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[3] PCP Regulations, s 1(1) "approved label", **ABA, Tab 21**

[4] Act, s 6(5), **ABA, Tab 20**

[5] Act, ss 2, 5, 7, 6(9), 69, **ABA, Tab 20**

[6] Act, s 4(1), **ABA, Tab 20**

[7] Act, ss 8(1), 8(4), **ABA, Tab 20**

[8] Act, s 7(6), **ABA, Tab 20**

[9] Act, s 2(2), **ABA, Tab 20**

[10] Act, s 2 "health risk", **ABA, Tab 20**

deemed conditions of registration by the Act or regulations.[11]

6. In making a decision regarding the registration of a pesticide, PMRA specifies the maximum amount of pesticide residue that can remain on each crop, or group of crops (the "maximum residue limit" or "MRL").[12] Where a registration decision is subject to public consultation, PMRA is directed to consider the following non-exhaustive factors in determining the MRL: aggregate exposure to the pesticide from diet and other sources; cumulative effects of the pesticide and other pesticide products; and the different sensitivities of vulnerable groups (e.g. infants, pregnant women).[13]

7. In practice, PMRA establishes MRLs based on the results of field trial studies conducted by registrants or sponsors of an application to register a pesticide or amend its registration. In such studies, the pesticide is applied to a crop according to the highest acceptable use set out in the instructions for use on the label or proposed label.[14] The maximum amount of residue expected to remain on the food product as a result of such usage is then calculated using a statistical method to assess all data generated in field studies. The estimated residue levels are always equal to, or higher than, the highest residue observed in those trials.[15] PMRA confirms that the consumption of the maximum potential amount of expected residues will not pose a concern to human health then establishes those levels as MRLs, which become legally binding conditions of registration.[16]

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[11] Act, s 2 "conditions of registration", **ABA, Tab 20**

[12] Act, s 9, s 11(1), **ABA, Tab 20**

[13] Act, s 11(2)(a), **ABA, Tab 20**

[14] Affidavit of Isabelle Pilote Affirmed June 27, 2019 ("Pilote Affidavit"), paras 19-21, **Appeal Book, Tab 8, pp 1011-1012**

[15] Pilote Affidavit, para 19, **Appeal Book, Tab 8, p 1011**

[16] "Maximum Residue Limits for Pesticides", Ex D to Affidavit of Mary Lou McDonald Affirmed April 18, 2019 ("McDonald Affidavit"), **Appeal Book, Tab 6D, p 178**; Act, s 11, **ABA, Tab 20**

8. The Act contains two post-registration review mechanisms: special reviews and re-evaluations. PMRA must initiate a special review if there are reasonable grounds to believe that the risk or the value of the product is unacceptable.[17] Anyone may request a special review, and PMRA must provide written reasons to the requester concerning its decision whether or not to initiate a special review.[18] PMRA must initiate a re-evaluation of every registered pesticide product no later than 16 years from the most recent major decision affecting that product's registration.[19] In addition, PMRA may initiate a re-evaluation at any time where it considers there has been a change in the information required or the procedure used for assessing the risk.[20]

9. During a re-evaluation, PMRA reviews the available scientific information and updates its risk assessment. PMRA releases, for public consultation, a summary of its evaluation of the risks and value of the product, together with PMRA's proposed decision. PMRA must consider any comments received in the consultation before making a final re-evaluation decision.[21]

10. At the conclusion of a re-evaluation, PMRA must confirm the registration if it determines that the health and environmental risks and the value of the pesticide are acceptable.[22] If PMRA does not consider the health or environmental risks to be acceptable it must either amend the registration, if the risks would be acceptable after the amendment, or cancel the registration.[23] PMRA publishes its final re-evaluation

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[17] Act, s 17, **ABA, Tab 20**. PMRA must initiate a special review unless the review can be incorporated into an ongoing post-market review (Act, s 17.1)

[18] Act, s 17(4)(5), **ABA, Tab 20**

[19] Act, s 16(2), **ABA, Tab 20**

[20] Act, s 16(1), **ABA, Tab 20**

[21] "A Decision Framework for Risk Assessment and Risk Management in the PMRA" Science Policy Note SPN2000-01 ("Risk Assessment SPN"), p 12, Ex B to McDonald Affidavit, **Appeal Book, Tab 6B, p 157**; Act, s 28, **ABA, Tab 20**

[22] Act, s 21(1), **ABA, Tab 20**

[23] Act s 21(2), **ABA, Tab 20**

decision.

11. Any person may file with the Minister a NOO to a final re-evaluation decision.[24] The NOO must set out the *scientific basis* for the objection along with any evidence in support of the objection, including scientific reports or test data.[25] Once PMRA receives a NOO, it *may* establish a panel of one or more individuals to review the re-evaluation decision and recommend whether the decision should be confirmed, reversed, or varied.

12. In determining whether to exercise its discretion to establish a review panel, the *Review Panel Regulations* (the "Panel Regulations") direct PMRA to consider:

> a) whether the information in the NOO raises scientifically founded doubt as to the validity of the evaluations, on which the re-evaluation decision was based, of the health and environmental risks and value of the pest control product; and,
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> b) whether the advice of expert scientists would assist in addressing the subject matter of the objection. [26]

13. Other than the requirement to consider these two factors, the Panel Regulations do not direct PMRA on how to exercise its discretion. If a review panel is not established, PMRA must provide notice of the decision to the objector, along with written reasons.[27]

b. Overview of PMRA's Approach to Human Health Risk Assessments

14. To assess the risk to human health from exposure to a pesticide, PMRA considers and compares the toxicology of the pesticide (what levels of exposure to the product are safe) and the exposure, including dietary exposure (what levels of

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[24] Act, s 35(1), **ABA, Tab 20.** NOO's may also be filed following a special review decision or a product registration decision that is subject to public consultation pursuant to s 28(1)(a).

[25] Panel Regulations, s 2(c)(d), **ABA, Tab 22**

[26] Panel Regulations, s 3, **ABA, Tab 2**

[27] Act, s 35(5), **ABA, Tab 20**

exposure to the pesticide will Canadians have from residues in food and water).[28] PMRA makes conservative assumptions throughout its heath evaluation in order to ensure that dietary exposure and the potential risk of a pesticide is not underestimated.[29]

i. Toxicology

15. For each PMRA-approved pesticide, PMRA establishes reference levels to indicate the amount of pesticide residue to which an individual could be exposed without harmful health effects. These are based on toxicological studies conducted on animals. To take into account uncertainties arising from extrapolating these animal studies' findings to humans, as well as varying degrees of sensitivities among the human population, reference levels are typically set at amounts of at least 100-fold less than the maximum amount found to cause no harmful effects in animals.[30]

16. The reference levels are expressed both in terms of how much an individual may be exposed to in a given day without harmful effects (the "Acute Reference Dose" or "ARfD") and how much an individual may be exposed to every day over a lifetime without harmful effects (the "Acceptable Daily Intake" or "ADI").[31] Accordingly, if an individual's dietary exposure to a pesticide is less than the established ARfD and ADI, PMRA is satisfied that the dietary exposure to the pesticide is acceptable and does not pose a risk to human health.[32]

ii. Dietary exposure

17. To determine dietary exposure, PMRA estimates the types and amounts of

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[28] Pilote Affidavit, para 14, **Appeal Book, Tab 8, p 1010**

[29] Pilote Affidavit, paras 15, 25, **Appeal Book, Tab 8, pp 1010, 1013-1014**

[30] Pilote Affidavit, para 15, **Appeal Book, Tab 8, p 1010**; see also : Risk Assessment SPN, p 6, Ex B to McDonald Affidavit, **Appeal Book Tab 6B, p 151**; "Proposed Re-evaluation Decision, Glyphosate", PRVD2015-01 ("Proposed Re-evaluation Decision"), p 2, **Appeal Book, Tab 29, p 2150**

[31] Pilote Affidavit, paras 15-17, **Appeal Book, Tab 8, pp 1010-1011**

[32] Pilote Affidavit, para 18, **Appeal Book, Tab 8, p 1011**

food and water consumed by Canadians that may contain a particular pesticide residue and then applies the MRL for each processed commodity, crop, or crop group so as to calculate likely total exposure. If higher MRLs have been established by other international authorities for the same food commodity, PMRA uses those higher values in calculating exposure to ensure that exposure is not underestimated. PMRA also makes a number of conservative assumptions to ensure that dietary exposure will not be underestimated, such as: assuming that residue levels at the time of consumption will be as high as those observed at harvest, when residue levels are at their highest; assuming 100% of any treatable crop has been treated; and assuming that all relevant crops, animal commodities, and drinking water in a person's diet contain residues of the pesticide.[33]

18. To determine the types and amounts of foods that may be treated with a pesticide that a person is likely to eat, both on a daily basis and over his or her lifetime, PMRA has relied on a proprietary database and software program developed by the United States Food and Drug Administration ("USFDA") in 2009 ("DEEM 2.14").[34] The program estimates food consumption, both for the entire population and for subgroups (such as women of child-rearing age) based on food surveys which were conducted in 1994-1996 and 1998.[35] This data allows for consumption to be examined by average consumption for the entire population or specific subgroups of the population.[36]

19. PMRA determines potential dietary exposure by examining all types and amounts of food that may be treated with a particular pesticide that a person is likely to eat both daily and in a lifetime (DEEM 2.14 data) and calculating the total potential pesticide residue exposure based on the highest residues observed for the commodity

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[33] Pilote Affidavit, para 25, **Appeal Book, Tab 8, pp 1013-1014**

[34] Pilote Affidavit, paras 28-29, **Appeal Book, Tab 8, p 1015**

[35] Pilote Affidavit, paras 28-29, **Appeal Book, Tab 8, p 1015**

[36] Pilote Affidavit, para 29, **Appeal Book, Tab 8, p 1015**

(typically the MRLs).[37]

c. Re-evaluation of Glyphosate

20. Glyphosate is an herbicide used for weed control in both agricultural crops and in non-agricultural land management.[38] Glyphosate has many beneficial applications, including, controlling weeds which might otherwise impede crop production; making harvesting easier and; reducing tillage after harvest which facilitates conservation agriculture and improves soil quality.[39] Glyphosate is registered for pre-harvest use on several crops including wheat, barley, oats, canola, flax, lentils, peas, dry beans, and soybeans. The pre-harvest application dries up, or desiccates, certain crops and green weeds in the field so as to facilitate harvesting. However, while glyphosate is registered for a pre-harvest (i.e. desiccating) application on some crops, it is not registered as a desiccant *per se* on any crop in Canada.[40]

21. In accordance with the Act, PMRA gave notice to the registrants in late 2009 of its intention to initiate a re-evaluation of glyphosate.[41] In February 2010, PMRA published a re-evaluation note, advising the public that it would be working with the United States Environmental Protection Agency ("USEPA") to conduct its re-evaluation.[42] In relation to human health, PMRA indicated:

a) Consideration would be given to any new toxicological data including data generated for the USEPA and in relevant published literature;

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[37] Pilote Affidavit, para 30, **Appeal Book, Tab 8, pp 1015-1016**

[38] Pilote Affidavit, para 7, **Appeal Book, Tab 8, p 1008**

[39] "Re-evaluation Decision Glyphosate", RVD2017-01 ("Final Re-evaluation Decision"), p 7, **Appeal Book, Tab 31, p 2494**

[40] Pilote Affidavit, para 35, **Appeal Book, Tab 8, p 1017**

[41] "Re-evaluation Work Plan for Glyphosate," REV2010-02 ("Re-evaluation Note"), Ex H to McDonald Affidavit, **Appeal Book, Tab 6H, p 240**

[42] Re-evaluation Note, Ex H to McDonald Affidavit, **Appeal Book, Tab 6H, p 240**

b) The assessment would include application of the Pest Control Products Act factors ("PCPA factors"), which are described in a Science Policy Note,[43]" and broadly outline PMRA's conservative approach to addressing uncertainty in conducting health risk assessments including as a result of extrapolating data obtained through animal testing;

c) Occupational and residential risk assessments would be reviewed if required;

d) Dietary risk is well below the levels of concern based on current modern assessments. New assessments would not be needed provided there are no changes to toxicology endpoints as a result of the PCPA factors; and

e) PMRA will conduct new assessments if required and share with the USEPA.[44]

i. Proposed Re-evaluation Decision

22. PMRA published its consultation document and Proposed Re-evaluation Decision on April 13, 2015.[45] The Proposed Re-evaluation Decision contains a detailed summary of PMRA's findings, which are further outlined in 12 appendices. In determining that the health and environmental risks of glyphosate were acceptable when used according to the proposed label directions, PMRA reviewed hundreds of studies from registrants and published sources.[46] PMRA considered well over 300 studies related to the dietary risk assessment, and more than 100 additional studies

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[43] "The Application of Uncertainty Factors and the PCPA Factor in Human Health Risk Assessment of Pesticides", Science Policy Note, SPN2008-01 ("Uncertainty and PCPA Factor SPN"), pp 10-13, Ex L4 to McDonald Affidavit, **Appeal Book, Tab 6L4, pp 428-431**

[44] Re-evaluation Note, Ex H to McDonald Affidavit, **Appeal Book, Tab 6H, pp 240-241**

[45] Proposed Re-evaluation Decision, **Appeal Book, Tab 29, p 2142;** Decision of Justice Simpson dated February 13, 2020 ("FC Decision"), para 8, **Appeal Book, Tab 2, p 14**

[46] Proposed Re-evaluation Decision, pp 250-323 itemizes the studies considered for each aspect of the risk assessment, **Appeal Book, Tab 29, pp 2398-2471**

related to toxicology.[47]

23. In finding that the health risks were acceptable, PMRA noted:

a) The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers) and health effects that were noted in animals occur at dosages more than 100 times (and often much higher) the levels to which humans are exposed;[48]

b) Animal toxicity tests and peer reviewed studies were used to assess the potential effects of glyphosate and the level of exposure to humans is well below the lowest dose at which effects occurred;[49]

c) While the World Health Organization identified glyphosate as "probably carcinogenic to humans" in its hazard classification, that classification is not a health risk assessment and does not take into account potential levels of exposure. Pesticides are only registered in Canada where PMRA determines the level of exposure does not cause harmful effects; [50]

d) Both the ADI and the ARfD demonstrated no risk of concern from dietary consumption for any group, including children and older adults;[51] and,

e) Risks in non-occupational environments (such as exposure from lawns and turf) were acceptable including when considering the aggregate risk from this potential exposure and dietary exposure.[52]

24. PMRA proposed two additional risk mitigation measures in relation to human health. First, to protect workers entering treated sites, it proposed a 12-hour restricted entry interval for agricultural uses. Next, to protect bystanders, it proposed an additional label statement informing users to apply only when potential for drift is

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[47] Proposed Re-evaluation Decision, pp 250-323, **Appeal Book, Tab 29, pp 2398-2471**

[48] Proposed Re-evaluation Decision, p 2, **Appeal Book, Tab 29, p 2150**

[49] Proposed Re-evaluation Decision, p 3, **Appeal Book, Tab 29, p 2151**

[50] Proposed Re-evaluation Decision, p 3, **Appeal Book, Tab 29, p 2151**

[51] Proposed Re-evaluation Decision, p 3, **Appeal Book, Tab 29, p 2151**

[52] Proposed Re-evaluation Decision, p 4, **Appeal Book, Tab 29, p 2152**

minimal.[53]

ii. Final Re-evaluation Decision

25. After considering and analyzing the information provided to PMRA during the public consultation period, which included hundreds of additional studies (nearly 200 of which related to toxicology), PMRA published its Final Re-evaluation Decision on April 28, 2017.[54] The decision concludes that the use of glyphosate in accordance with revised labels poses no unacceptable risks to human health or the environment.[55]

26. In respect of health risks, PMRA noted glyphosate is unlikely to cause cancer, dietary exposure associated with glyphosate is not expected to pose a risk of concern to human health, and occupational and residential risks are not of concern provided updated label amendments are followed. In particular, PMRA found:

a) Dietary risks were not of concern for any age group as the reference levels of acceptable exposure (ADI and ARfD) were well above the maximum levels of potential exposure;[56]

b) Non-occupational risks (for example, exposure from treated lawns and hiking in treated areas) are not of concern when used according to label directions;[57] and,

c) Occupational risks to handlers of glyphosate are not of concern when used in accordance with the label instructions.[58]

27. The Final Re-evaluation Decision includes a summary of the public comments received along with PMRA's responses. In relation to public health, PMRA provided further information concerning its assessment of the toxicity of glyphosate, including its assessment of the acceptable reference levels with regard to additional

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[53] Proposed Re-evaluation Decision, p 7, **Appeal Book, Tab 29, p 2155**

[54] Final Re-evaluation Decision, **Appeal Book, Tab 31, p 2483**

[55] Final Re-evaluation Decision, p 2, **Appeal Book, Tab 31, p 2489**

[56] Final Re-evaluation Decision, p 4, **Appeal Book, Vol 31, p 2491**

[57] Final Re-evaluation Decision, p 5, **Appeal Book, Vol 31, p 2492**

[58] Final Re-evaluation Decision, pp 5-6, **Appeal Book, Tab 31, pp 2492-2493**

studies submitted.[59]

28. Consistent with the Proposed Re-evaluation Decision, PMRA continued the registration of glyphosate but required certain label amendments. Amendments arising from the health assessment include directions that users apply a 12-hour restricted entry interval for agricultural uses and ensure the potential for drift is minimal before applying the products in areas of human activity.[60]

iii. Appellant's Notice of Objection

29. The Appellant filed a NOO enumerating nine objections to the Final Re-evaluation Decision.[61] PMRA reviewed the NOO and determined that the objections did not raise a scientifically founded doubt as to the validity of PMRA's evaluations of the health and environmental risk of glyphosate, and, that the advice of expert scientists would not assist it in addressing the subject matter of the objections.[62] PMRA provided a response to the NOO, outlining its reasons for decision. In addition to its written response, PMRA hosted a technical briefing with Objectors, including the Appellant, to outline the rationale for PMRA's decision.[63] The Appellant requested additional documentation at this briefing, which PMRA subsequently provided.[64]

30. The NOO indicated that the main basis of the objection (Objections 1 to 4) was MRL exceedances that the Appellant contended may occur when glyphosate is applied for desiccation (i.e. pre-harvest) purposes, which the Appellant asserted was of particular concern given increased consumption of products from one of these

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[59] Final Re-evaluation Decision, pp 15-23, **Appeal Book, Tab 31, pp 2502-2510**

[60] Final Re-evaluation Decision, p 74, **Appeal Book, Tab 31, p 2561**

[61] Notice of Objection dated June 27, 2017 ("NOO"), Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, pp 369-389**

[62] PMRA's Response to Notice of Objection dated January 11, 2019 ("Response to NOO"), pp 1-2, **Appeal Book, Tab 4, pp 54-61**

[63] McDonald Affidavit, para 30, **Appeal Book, Tab 6, p 77**

[64] Email from Health Canada in response to inquiry by Mary Lou McDonald, Ex O to McDonald Affidavit, **Appeal Book, Tab 6O, p 807**

desiccated crops, chick pea. In response PMRA noted:

a) MRLs were in place for all relevant food crops and the dietary risk assessment encompassed all food uses for which glyphosate is registered for use;[65]

b) Glyphosate residue levels were measured in field studies based on actual use of glyphosate in accordance with the legally binding conditions of registration;[66]

c) Any exceedance of the MRL is an offence and is enforceable under the *Food and Drugs Act*;[67]

d) MRLs are set at levels well below the amount of residue that could cause a concern for human health and, while an exceedance of an MRL does not necessarily result in health concerns, the Canadian Food Inspection Agency ("CFIA") initiates follow-up compliance measures;[68]

e) The few MRL exceedances identified by the CFIA were not a concern to human health;[69]

f) All registered product uses on food crops were considered in the risk assessment, including desiccated crops, which are pre-harvest applications;[70] and

g) Dietary exposure estimates are well below the acceptable reference levels (ADI and ARfD), and those estimated exposure levels are overestimated because they are set assuming all crops are treated and further assume the highest residue level for each type of use (for example desiccated crops).[71]

31. The fifth objection, as outlined in the NOO, was that the labels do not address the risk identified in Objections 1 to 4, because they cannot ensure glyphosate will not

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[65] Response to NOO, pp 6-7, **Appeal Book, Tab 4, pp 59-60**

[66] Response to NOO, pp 4-5, **Appeal Book, Tab 4, pp 57-58**

[67] Response to NOO, p 4, **Appeal Book, Tab 4, p 57**

[68] Response to NOO, pp 4-5, **Appeal Book, Tab 4, pp 57-58**

[69] Response to NOO, p 7, **Appeal Book, Tab 4, p 60**

[70] Response to NOO, p 5, **Appeal Book, Tab 4, p 58**

[71] Response to NOO, pp 5-6, **Appeal Book, Tab 4, pp 58-59**

be applied to crops with high moisture levels or to immature crops.[72] In response, PMRA noted that the label instructions, which are legally binding on users, specifically direct users to consider both moisture content (30%) and physical indicators of maturity.[73]

32. Objections 6 to 8 also related to potential non-compliance with the label instructions. As these objections did not raise any scientific issue, they could not raise any scientific doubt concerning the validity of PMRA's evaluations, nor could the advice of scientific experts assist PMRA in resolving these issues.[74] They are beyond the purview of the NOO procedure.[75]

33. With respect to the reduction of the PCPA Factor, noted in Objection 9, PMRA responded that, in determining whether to reduce the PCPA Factor, it considered contextual information.[76] For example, PMRA took into account that assessing potential harm to a maternal animal will overlap with the assessment of fetal toxicity, because protecting maternal health can limit fetal exposure in some instances. Having regard to the data before it, and considering the completeness of the data along with potential effects on vulnerable populations, PMRA found the PCPA Factor could be reduced.[77]

C. THE JUDICIAL REVIEW

34. The Appellant commenced an application for judicial review challenging the

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[72] NOO, Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, at p 379**

[73] Response to NOO, p 7, **Appeal Book, Tab 4, p 60**

[74] Pilote Affidavit, para 63, **Appeal Book, Tab 8, pp 1027**

[75] Panel Regulations, s 2(c), 3(a), **ABA, Tab 22**

[76] Response to NOO, p 3, **Appeal Book, Tab 4, p 56**

[77] Response to NOO, p 3, **Appeal Book, Tab 4, p 56;** see also: Proposed Re-evaluation Decision, pp 16-17, **Appeal Book, Tab 29, pp 2164-2165;** Final Re-evaluation Decision, pp 27-28; **Appeal Book, Tab 31, pp 2514-2515**

lawfulness of PMRA's response, noting in particular Objections 1 to 4 and 6 to 9.[78] Justice Simpson dismissed the application. She concluded that the Appellant failed to raise an issue of scientific doubt concerning the validity of PMRA's evaluations such that PMRA's decision not to appoint a review panel to assist it in addressing any issue of scientific doubt was not unreasonable.[79]

35. In this appeal, the Appellant focuses on Objections 1 to 3 and 5, namely, residue levels and possible MRL exceedances for desiccated crops. Regarding these issues, Justice Simpson noted that PMRA indicated in its response to the NOO that it had reviewed all of the studies submitted by the Appellant.[80] She further noted that PMRA's conclusions were not inconsistent with those studies given the label instructions already imposed on users – namely, not to apply to crops with more than 30% moisture or to immature crops (having regard to both moisture levels and visual evaluation).[81] Lastly, she referenced PMRA's assessment of MRL exceedances, noting the data before PMRA indicated MRL exceedances in only 1.3% of 3,188 crops tested. She found PMRA's conclusion that those exceedances posed no risk to human health reasonable.[82]

II. ISSUES

36. As the parties agree that the Application Judge identified the appropriate standard of review and further agree this Court 'stands in the shoes' of the reviewing judge, the only issue in this appeal is whether the Application Judge erred in finding that PMRA's decision to decline to appoint a review panel was reasonable. In determining this issue, the appellate court is to focus on the administrative decision,

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[78] Notice of Application, **Appeal Book, Tab 3**

[79] FC Decision, paras 19, 74, **Appeal Book, Tab 2, pp 22, 37**

[80] FC Decision, para 33, **Appeal Book, Tab 2, p 27**

[81] FC Decision, para 33, **Appeal Book, Tab 2, p 27**

[82] FC Decision, paras 35-37, **Appeal Book, Tab 2, p 28**

rather than the lower court decision.[83]

III. LAW AND SUBMISSIONS

37. Having regard to the nature of the decision at issue, its relationship to the general statutory framework and the broad discretion afforded to the PMRA under the Panel Regulations, PMRA's decision – as detailed in its Response to the NOO – was reasonable.

A. PMRA'S DECISION IS CONSISTENT WITH THE STATUTORY SCHEME

a. Nature of the Requisite Reasonableness Review

38. The parties agree the Application Judge was correct to apply the standard of review of reasonableness. The factors that justify the presumption of a reasonableness standard – legislative supremacy, the democratic principle, respect for legislature's choice to delegate authority to an administrative body, and the need for courts to avoid "undue interference" with the decision maker's discharge of its functions – required the Application Judge (and require this Court) to adopt a posture of restraint. [84]

39. The role of the court is to review, not to decide the issue itself. The reviewing court does not ask what decision it would have made in place of that of the administrative decision maker, attempt to ascertain the range of possible conclusions that would have been open to the decision maker, conduct a *de novo* analysis or seek to determine the correct solution to the problem. Instead, it must consider only whether the decision made by the administrative decision maker – including both the rationale

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[83] *Agraira v Canada*, 2013 SCC 3 at para 46, citing *Merck Frosst Canada Ltd v Canada (Health)*, 2012 SCC 3 at para 247, **ABA, Tab 3**; *Jog v Bank of Montreal*, 2020 FCA 218 at para 3, **Attorney General of Canada's Book of Authorities, "AGC-BA"), Tab 1**

[84] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 ["*Vavilov*"] at paras 13, 24-25, 30, **ABA, Tab 1**; *Dunsmuir v New Brunswick*, 2008 SCC 9 at para 27, **AGC-BA, Tab 2**

for the decision and the outcome to which it led – was reasonable.[85]

40. Although expertise is no longer relevant to determining the standard of review, it is among the reasons why a legislature may delegate decision-making authority[86] and it therefore remains a relevant factor in conducting a reasonableness review.[87]

41. A reasonable decision is one that is transparent, intelligible, and justified in relation to the factual and legal constraints that bear on the decision.[88] The Supreme Court of Canada and this Court have both recognized that constraints operating on decision makers are varied and contextual, and will constrain administrative decision makers to varying degrees.[89] For example, decision makers applying fact-driven criteria of a non-legal (or less legal) nature are less constrained, as are decision makers in whom is vested a broad scope of discretion.[90] Decision makers who make complex, multifaceted assessments drawn from their expertise or specialization are also less constrained.[91]

42. The Appellant seeks to characterize the relevant statutory regime in this case as containing strict and specific directions that govern when PMRA is to establish a review panel. Similarly, the Interveners argue that anything but a low threshold for establishing such panels would improperly shift the statutory onus to the objector from the registrant of the pest control product. These characterizations are unsustainable.

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[85] *Vavilov* at paras 83 and 116, **ABA, Tab 1**

[86] *Vavilov* at paras 29, 30, **ABA, Tab 1**

[87] *Vavilov* at paras 31, 93, **ABA, Tab 1**

[88] *Vavilov* at para 99, **ABA, Tab 1**

[89] *Vavilov* at paras 90 and 105, **ABA, Tab 1**; *Entertainment Software Association v Society of Composers, Authors and Music Publishers of Canada,* 2020 FCA 100 ("*Entertainment Software*") at para 24, **ABA, Tab 6**

[90] *Entertainment Software* at paras 27-28, 31-32, **ABA, Tab 6**

[91] *Entertainment Software* at paras 29-30, **ABA, Tab 6**

43. In determining whether to appoint a review panel, PMRA's discretion is broad and fact-driven, and its limitations are narrowly prescribed. Further, PMRA reviews a NOO in circumstances where a final decision has been made, such that the statutory onus on the registrant has been discharged. When filing a NOO with PMRA, it is the objector's burden to demonstrate a scientifically founded doubt. To that end, the objector is required to include with its NOO, among other things, the scientific basis for its objection to PMRA's evaluations and the evidence in support of its objection, including scientific reports or test data.[92] PMRA properly considers the NOO in light of all of the information that has already been filed and assessed. In essence, PMRA considers – as the Panel Regulations direct it to – whether anything raised in the NOO causes PMRA to doubt its prior evaluations.

b. Statutory Scheme

44. There is no dispute that scientific rigor and public consultation are important aspects of the governing regime. It was consistent with those priorities, and in accordance with the directives and discretion set out in the Act, that PMRA undertook the glyphosate re-evaluation. PMRA reviewed hundreds of scientific studies, presented its analysis for public consultation in a detailed Proposed Re-evaluation Decision and published its Final Re-evaluation Decision, including its comments on the hundreds of additional studies submitted or referred to during the consultation.

45. Throughout any re-evaluation process (or, for a proposed product, throughout PMRA's review of an application for registration), the onus is on the registrant (or applicant, for a new registration) to satisfy PMRA that the health and environmental risks and the value of the pest control product are acceptable.[93] The Interveners equate this with a statutory "presumption" against the registration of a pest control product. This overstates the Act's requirements. The purpose of the Act is the regulation, not

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[92] Panel Regulations, s 2(c) and (d), **ABA, Tab 22**

[93] Act, s 8(1), s 8(4), s 21(1), 21(2) **ABA, Tab 20**

the prohibition, of pest control products.[94] If PMRA concludes that the product's risks and value are acceptable then it must register the product (if new) or must confirm its registration (if the product has been re-evaluated).[95] While the Act establishes regulatory requirements for initial registrations and subsequent confirmations of registration, this simply does not amount to a "fundamental presumption" against them.[96]

46. Following the complex and extensive re-evaluation process, section 35 of the Act establishes a further process triggered by a NOO. In particular, upon receipt of a NOO, subsection 35(3) gives PMRA the discretion to establish a panel to undertake a further review of its Final Re-evaluation Decision. The Act prescribes no restriction on the exercise of PMRA's discretion in this regard. The only express limit on its discretion is that, in reaching its conclusion, PMRA must "take into account" the two factors set out in section 3 of the Panel Regulations. That is, it must consider: (i) whether the notice of objection raises "scientifically founded doubt" as to the validity of the evaluations of the health risks and (ii) whether the advice of scientific experts would assist in addressing the subject matter of the objection.[97]

47. While PMRA is directed to consider these two factors in rendering its decision on whether or not to establish a review panel, the Panel Regulations do not otherwise direct PMRA in how to exercise its discretion. The Panel Regulations do not prescribe, for example, how PMRA is to assess or weigh these factors, nor does it exclude other factors from PMRA's consideration.

48. In considering the statutory context relevant to PMRA's exercise of statutory discretion pursuant to section 35 of the Act, it is critical to keep in mind all that has occurred up to the point of filing a NOO and, in particular, the rigor of the analysis

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[94] *David Suzuki Foundation v Canada (Health)*, 2019 FC 1637 at para 97-98, **AGC-BA, Tab 3**

[95] Act, s 8(1), s 21(1), **ABA, Tab 20**

[96] Memorandum of Fact and Law of the Interveners, para 15

[97] Panel Regulations, s 3, **ABA, Tab 21**

that has taken place. PMRA's scientific evaluations throughout the re-evaluation process result in PMRA determining whether or not the product's health and environmental risks, and its value, are acceptable, taking into account any stipulated mitigation measures or conditions of registration. In other words, PMRA determines whether or not the registrant has met its onus. It is inaccurate for the Interveners to speak of the NOO process as potentially shifting the onus from the registrant to the objector, as the statutory burden on the registrant has been discharged by the time the NOO process commences. The burden on an objector is distinct and must take into account the rigorous re-evaluation process that precedes the NOO.

49. The Appellant criticizes PMRA for failing to explicitly articulate its interpretation of the "doubt" contemplated by subsection 3(a) of the Panel Regulations or the "evaluations" with respect to which such doubt is to be raised. However, decision makers are not required to undertake a formalistic statutory interpretation exercise that enumerates every single possible consideration. An administrative decision maker's written reasons need not include all the arguments, statutory provisions, jurisprudence and related details that the court may have preferred.[98] Rather, the decision maker's interpretation must be consistent with the text, context, and purpose of the relevant statute, and the decision maker's reasons must demonstrate that they were alive to these essential elements.[99]

50. In this case, the essential elements of the Act and Panel Regulations include the broad discretion afforded to PMRA, the factual and deeply scientific nature of the issues, PMRA's specialized expertise, and the compilation and assessment of substantial information in the course of the entire re-evaluation process. These elements indicate that it falls to PMRA to conduct a fact-based inquiry and determine on a case-by-case basis whether a NOO raises for PMRA a scientifically founded doubt about the evidence or analysis underlying the decision it rendered. Here, PMRA

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[98] *Vavilov* at para 91, **ABA, Tab 1** citing *NLNU v Newfoundland & Labrador (Treasury Board)*, 2011 SCC 62 at para 16, **AGC-BA, Tab 4**

[99] *Vavilov* at para 120, **ABA, Tab 1**

was clearly alive to these essential elements by virtue of how it applied them. Its reasons demonstrate that it carefully considered each scientific objection raised by the Appellant, reviewed the scientific information (both referred to in the NOO and underlying its Final Re-evaluation Decision) and provided thorough and thoughtful responses.

i. "Scientifically Founded Doubt"

Controlled Peer-Reviewed Studies are Relevant but not Determinative

51. Much of Appellant's argument, and virtually all of Interveners' argument, is directed to the Application Judge's finding that scientifically founded doubt must be demonstrated by at least one controlled peer-reviewed study. There is no indication that PMRA applied such a requirement. To the contrary, PMRA, for example, reviewed and provided a detailed response to the non-peer-reviewed literature submitted with the NOO regarding the application of glyphosate to crops with high moisture content. PMRA pointed out in its response to the NOO that the literature submitted by the Appellant identified an optimum moisture content for application of glyphosate that coincided with the label requirements.[100] Further, not all peer-reviewed studies will necessarily warrant the appointment of a review panel. Indeed, any mandatory criterion is at odds with the broad and factual nature of PMRA's discretion. This Court need not endorse the requirement for a controlled, peer-reviewed study in order to uphold the Application Judge's conclusion that PMRA's decision was reasonable.

52. However, the Application Judge's reference to controlled peer-reviewed studies is – if not a proper stipulation – at least a meaningful example of the type of information that could raise a scientifically founded doubt. PMRA uses a "weight of evidence" approach in assessing scientific data.[101] For example, in the public consultation regarding the Proposed Re-evaluation Decision, certain information was submitted to PMRA that was derived from websites or general publications of non-

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[100] Response to NOO, Comment 2, p 4, **Appeal Book, Tab 4, p 57**

[101] Final Re-evaluation Decision, pp 28-29, **Appeal Book, Tab 31, pp 2515-16**

governmental organizations or independent researchers. PMRA noted that such documents consolidated a wide range of sources including studies that were of low quality and reliability, or that failed to use accepted methodologies.[102] The relevance of such studies was therefore diminished under a weight-of-evidence approach. Applying the same approach to the question of whether a NOO has raised a scientifically founded doubt, it would be reasonable to accord greater weight to a controlled, peer-reviewed study than to other sources such as a newspaper article or website opinion piece.

53. Similarly, a single, stand-alone peer-reviewed study may not cast "scientifically founded doubt" on PMRA's evaluation where there are multiple other peer-reviewed studies that have a different finding or reach a different conclusion. PMRA must be free to consider the "weight of evidence" and that evidence must include all of the information assessed for the re-evaluation. In this sense, as the Interveners point out, there may be *some* similarities between PMRA's approach to determining whether a review panel is warranted under section 35 of the Act and its approach to determining whether a special review of a registered product is warranted under section 17 of the Act.

54. In particular, several of the Federal Court's comments in *Wier*[103] concerning PMRA's evaluation of evidence in a special review would apply to PMRA's assessment of NOOs. For example, the Court found that the requester's evidence must be evaluated in light of PMRA's existing knowledge, including all of the evidence already in its possession, and that PMRA properly focused its inquiry on "whether the evidence changed any of the analysis that had already been undertaken at the time that the pesticides were registered".[104] Further, in determining whether, under section 17, there are "reasonable grounds" to believe that a product's risk or value is unacceptable,

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[102] Final Re-evaluation Decision, pp 28-29, **Appeal Book, Tab 31, pp 2515-16**

[103] *Wier v Canada (Minister of Health)*, 2011 FC 1322 ("*Wier*"), **Book of Authorities of the Intervenors ("Int-BA"), Tab 3**

[104] *Wier* at para 88, **Int-BA, Tab 3**

the Court found that PMRA would require "compelling and credible evidence that gives rise to a serious possibility" that the pesticide may cause unacceptable risk.[105]

55. There are, of course, notable differences in the provisions governing the two processes. For example, PMRA *must* initiate a special review where it has "reasonable grounds to believe" that the risks of a product are unacceptable.[106] This is quite distinct from the discretion afforded to PMRA to *consider*, among other factors, whether a NOO raises "scientifically founded doubt" about PMRA's evaluations. As PMRA has broader discretion in the context of NOOs than in the context of special reviews, the constraints are lesser.

56. Within this context, it is reasonable, and entirely consistent with the statutory scheme, that PMRA consider NOOs against its existing knowledge, including all of the evidence already in its possession as a result of the re-evaluation process. Further, and taking into account that the Panel Regulations refer to "scientifically founded doubt", it is reasonable that PMRA require some form of compelling and credible *scientific* evidence to cast doubt on PMRA's detailed risk assessment.

"Reasonable Doubt" is not Relevant

57. The Appellant argues that the meaning of "doubt" in section 3 of the Panel Regulations should be informed by the concept of "reasonable doubt", a legal term of art rooted in criminal law. The Appellant relies on the proposition that a word having particular meaning in common law carries that meaning in a statute in the absence of an indication that Parliament intends otherwise.[107] In this case, however, there are a number of indications that in enacting the Panel Regulations the GIC had no intention of importing concepts associated with the doctrine of reasonable doubt.

58. First, the provision does not speak of "reasonable doubt", a term specifically

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[105] *Wier* at para 97, **Int-BA, Tab 3**

[106] Act, s 17(1), s 17(4), **ABA, Tab 20**

[107] Memorandum of Fact and Law of the Appellant, para 54

used in a number of federal legislative provisions outside of the *Criminal Code*,[108] but rather speaks of "scientifically founded doubt". Second, it uses that term in the context of a regulation that affords broad discretion to a decision maker, which has considerable scientific expertise. Third, the term is to be employed by the decision maker not in gauging the burden of proof in an adjudicative forum but in making a weight-of-evidence assessment of the scientific substance of the NOO's objection to a decision that has already been made – a decision that is the culmination of a rigorous scientific analysis and that considers all comments, including scientific evidence received during the public consultation. It is not sufficient or in keeping with the statutory context that the doubt contemplated by subsection 3(a) need only be more than "an imaginary or frivolous doubt" that is based upon "reason or common sense".[109]

59. Further, it is notable that under section 35 of the Act, PMRA *may* appoint a review panel and, if appointed, the review panel makes a recommendation as to whether *PMRA* should confirm, reverse or vary its decision. That is, it is intended that the review panel contribute to PMRA's consideration of the issues raised in the NOO. As such, it is from PMRA's perspective that the question of whether a review panel is "necessary" must be considered under section 3 of the Panel Regulations. Accordingly, where subsection 3(a) directs PMRA to consider whether the information in the NOO raises a scientifically founded doubt as to the validity of the evaluations, the relevant doubt must be *for* PMRA (not for a hypothetical reasonable person). Here, PMRA did not have any doubt as to the scientific validity of the evaluations underlying the decision and also concluded that external expert advice would not assist it in addressing the subject matter of the objection. Accordingly, it did not exercise its discretion to appoint a review.

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[108] See, for example: *Canada Elections Act*, SC 2000, c 9, s 144; *Diplomatic Service (Special) Superannuation Act*, RSC 1985, c D-2, s 13(1); *Wild Animal and Plant Trade Regulations*, SOR/96-263, s 20; *Veterans Well-being Regulations*, SOR/2006-50, s 52

[109] *R v Lifchus*, [1997] 3 SCR 320 at para 36, **ABA, Tab 12**

ii. Validity of "Evaluations"

60. In subsection 3(a) of the Panel Regulations, the question for PMRA is whether "scientifically founded doubt" has been raised in reference to the "validity of the evaluations" on which the decision was based. The Appellant claims that PMRA, in reviewing the NOO, did not consider the underlying scientific "evaluations" at all but, rather, considered only the "issues raised" by the NOO. This claim is misguided, as the issues raised in the NOO are expressly directed at the evaluations that PMRA undertook in the re-evaluation (or that the Appellant alleged PMRA failed to undertake). Accordingly, PMRA's reference to its consideration of the "issues raised" by the NOO necessarily encompassed the faults that the Appellant alleged in the underlying evaluations. The Appellant's focus on PMRA's reference to the "issues raised" is a parsing of language that disregards the detailed context of the response to the NOO.

61. In any event, the evaluations undertaken by PMRA, as set out in the Proposed Re-evaluation Decision, assess the level of risk of the product. As the Application Judge found, an NOO is a vehicle for scientifically-based challenges to the PMRA's evaluations, such that the decision not to appoint a review panel would be unreasonable only if the Appellant's NOO showed a well founded scientific doubt about a conclusion in the evaluations.[110] If none of the Appellant's criticisms, or "issues", and accompanying evidence raised scientific concerns that would affect the outcome of the risk assessment, then there would be no doubt about the "validity of the evaluations". Again, PMRA's interpretation of the provision in this manner is demonstrated by its actions. The response to the NOO clearly evidences that PMRA considered whether the Appellant's allegations regarding PMRA's evaluations had any scientific merit. PMRA responded in detail to each scientific allegation, with reference to the data underlying PMRA's evaluations, and determined that the NOO did not raise any scientific doubt about the validity of the conclusions reached in the risk assessment. The determination was a reasonable one.

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[110] FC Decision, paras 17-19, **Appeal Book, Tab 2, p 21-22**

B. PMRA REASONABLY ADDRESSED THE OBJECTIONS

62. PMRA carefully considered each scientific objection raised by the Appellant and provided thoughtful and thorough responses to those objections. PMRA ultimately found that the objections did not raise a scientifically founded doubt as to PMRA's evaluation of glyphosate's potential risk to human health and that a review panel would not assist it in addressing any of the issues raised by the Appellant. On this basis, PMRA declined to appoint a review panel.

63. While the Appellant's Notice of Application focused on objections 1 to 4 and 6 to 9, the Appellant now focuses on the reasonableness of PMRA's response to Objections 1 to 3 and Objection 5. These objections relate to PMRA's assessment of residue levels in respect of certain crops and its estimate of dietary consumption. As Justice Simpson found, PMRA's conclusions in all respects are justified, intelligible and transparent. There is no basis for this Court's interference.

a. PMRA Properly Considered How Both Moisture and Maturity Affect Residue Levels (Objections 1, 2 and 5)

64. As the Appellant acknowledges, both in the NOO and in its Memorandum of Fact and Law, the issues of moisture content and physiological maturity are closely related. As seeds mature, seed moisture content reduces, and the resulting residue from a glyphosate application will be lower than it would be in immature seeds with higher moisture content.[111] While the Appellant notes that moisture can also be affected by environmental conditions, like rainfall, the effect is that moisture content is a better indicator of when to apply glyphosate than physiological maturity as it accounts for both maturity and precipitation.

65. After reviewing Objections 1, 2, and 5, including the studies submitted in support of these objections, PMRA concluded that the objections did not raise a scientifically founded doubt with respect to PMRA's evaluations of the health risks of

[111] NOO, Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, p 379;** Memorandum of Fact and Law of the Appellant, para 82

glyphosate.[112] In particular, consistent with PMRA's evaluations, none of the studies submitted by the Appellant found that an application of glyphosate in accordance with the label instructions would result in residues higher than that of Canadian MRLs.[113] Moreover, none of these studies includes any assessment of whether the glyphosate levels the authors found would pose a risk to human health.[114] As Justice Simpson correctly found, these studies do not demonstrate any health concern if glyphosate is applied according to the current conditions of registration.[115]

i. Objection 1

66. Objection 1 of the NOO alleged that glyphosate's use as a desiccant can cause MRL exceedances, which in turn can pose a risk to human health and that the CFIA had documented MRL exceedances on crops in Canada. The Appellant now alleges that the PMRA did not meaningfully grapple with the submissions set out in Objection 1 of the NOO because PMRA dealt only with the moisture content of plants that receive desiccant applications rather than their "physiological maturity" at the time of application.

67. In responding to the NOO, PMRA clarified that it specifically considered pre-harvest (i.e. desiccant) applications, directing the Appellant to the relevant appendix in the Proposed Re-evaluation Decision.[116] While PMRA's response to the NOO focused on moisture content, there is a direct relationship between moisture content

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[112] Response to NOO, Cover Letter, Comments 2-4, 6, pp 1-2, 4-7, **Appeal Book, Tab 4, pp 54-55, 57-60**

[113] Response to NOO, Comment 2, pp 4-5, **Appeal Book, Tab 4, pp 57-58**; NOO, Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, pp 371-372**; Studies at Ex L to McDonald Affidavit, Tabs L3, L7-L9, L-12, and L-13, **Appeal Book, Tabs 6L3, 6L7-6L9, 6L12, 6L13**; Corrected Ex L1 to McDonald Affidavit (Cessna Study), **Appeal Book, Tab 35**

[114] Studies at Ex L to McDonald Affidavit, Tabs L3, L7-L9, L-12, and L-13, **Appeal Book, Tabs 6L3, 6L7-6L9, 6L12, 6L13**; Corrected Ex L1 to McDonald Affidavit (Cessna Study), **Appeal Book, Tab 35**

[115] FC Decision, paras 45-48, **Appeal Book, Tab 2, pp 30-31**

[116] Response to NOO, Comment 3, p 5, **Appeal Book, Tab 4, p 58**

and maturity. Indeed, the NOO itself clearly linked the two concepts.[117] The label requirements for a pre-harvest, or desiccant, application of glyphosate stipulate moisture levels but also expressly require that the pods be "mature" before being treated.[118] The label further provides physical cues to assist users in determining the appropriate physiological maturity of the plant before applying glyphosate.[119] PMRA pointed this out in responding to the NOO, noting that labels direct that pre-harvest applications are to be made at a specific plant growth stage that corresponds to 30% or less moisture content, and that the labels include pictographs to illustrate growth stage.[120]

68. Regarding the MRL exceedances alleged in the NOO, PMRA indicated in its response that the few glyphosate exceedances found by the CFIA (which regularly monitors MRL levels) did not raise a concern with respect to glyphosate's impact on human health.[121] In particular, the CFIA tested a total of 3,188 crop and food product samples for glyphosate and found that 98.7% of products were compliant with the relevant MRL.[122] PMRA conducted a further risk assessment to determine if the few MRL exceedances found in various crops posed a risk to human health. After conducting this additional assessment, PMRA found that there would be no significant increase in dietary exposure to glyphosate and that these exceedances did not indicate

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[117] NOO, Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, p 370** ("[T]he earlier glyphosate is applied as a desiccant or the more moisture content there is in the plant, the higher the residue levels in the plant.")

[118] "Product Label of Roundup WeatherMax", section 9.9, **Appeal Book, Tab 11, pp 1237-1240**

[119] Product Label of Roundup WeatherMax", section 9.9, **Appeal Book, Tab 11, pp 1238-1239**

[120] Response to NOO, Comment 6, p 7, **Appeal Book, Tab 4, p 60**

[121] Response to NOO, pp 4-5, **Appeal Book, Tab 4, pp 57-58**

[122] CFIA Report, p 1-2, **AB, Tab 6M, pp 1-2.**

a risk to human health.[123]

ii. Objection 2

69. In the NOO, the Appellant alleged that the Proposed Re-evaluation Decision did not consider the "harvest management or desiccation applications of glyphosate" and claimed that consideration of the risks associated from dietary exposure to desiccated crops was necessary to determine the risks to human health.[124] However, the Proposed Re-evaluation Decision explicitly states that the PMRA *did* consider all registered applications of glyphosate, including pre-harvest (i.e. desiccation) applications, when conducting its dietary risk assessment.[125] In response to the NOO, PMRA once again confirmed that they considered whether dietary exposure to crops that have been desiccated with glyphosate would cause a risk to human health.[126]

iii. Objection 5

70. While the Appellant now asserts that the basis of Objection 5 was that indeterminate plants always have seeds with moisture above 30%,[127] this was not articulated in the NOO and was therefore not expressly considered by PMRA.[128] Nor was it considered by the Application Judge, as the Appellant did not raise any allegations concerning Objection 5 in the Notice of Application.

71. On its face, Objection 5 alleges that higher residue levels of glyphosate

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[123] Pilote Affidavit, paras 43-46, **Appeal Book, Tab 8, pp 15-16**; "Email from P. Brander with CFIA data analysis, January 16, 2019", Ex O to McDonald Affidavit, **Appeal Book, Tab 6O, pp 809-810**

[124] NOO, Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, p 342**

[125] Proposed Re-evaluation Decision, Appendix V, p 99, **Appeal Book, Tab 29, p 2247;** Pilote Affidavit, para 51, **Appeal Book Tab 8, p 1023**

[126] Response to NOO, p 5, **Appeal Book, Tab 4, p 58**; Proposed Re-evaluation Decision, Appendix V, p 99, **Appeal Book, Tab 29, p 2247**

[127] Memorandum of Fact and Law of the Appellant, at paras 88-90

[128] NOO, Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, p 379;** see also: FC Decision, para 32, **Appeal Book, Tab 2, p 27**

caused by high moisture content cannot be mitigated by label directions.[129] In response to the Objection as framed in the NOO, PMRA noted that moisture content due to the maturity of some crops may result in exceedances.[130] PMRA assessed the scientific literature referred to in the NOO. PMRA noted the literature concluded that glyphosate residues increase when applied as a pre-harvest treatment to crops with a moisture content of more than 30%, which was consistent with the proper label usage for glyphosate.[131] Label instructions require glyphosate to be applied when there is *less than* 30% moisture content.

72. Label instructions are conditions of registration and a user's failure to follow them is an offence punishable by fine, imprisonment, or administrative monetary penalty.[132] Further, PMRA, when determining the acceptability of a product for an evaluation or re-evaluation decision, must take into account the conditions or proposed conditions of registration (as expressly set out in the definition of 'acceptable risk' under the Act), which users are bound to follow. Compliance issues are beyond the scope of the NOO procedure, which requires objectors to outline the scientific basis for their objection.[133]

b. PMRA's Assessment of Dietary Consumption was Reasonable (Objection 3)

73. The dietary consumption information used by PMRA in the re-evaluation of glyphosate was from the proprietary database DEEM 2.14, which used survey data that was gathered in 1994-1996 and 1998. The Appellant alleges that this was unreasonable.

74. When PMRA initiated its re-evaluation of glyphosate, DEEM 2.14 was the

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[129] NOO, Ex K to McDonald Affidavit, **Appeal Book, Tab 6K, p 379**

[130] Response to NOO, Comment 2 and 6, pp 4-5, 7, **AB, Tab 4, p-57-58, 60**

[131] Response to NOO, p 4, **AB, Tab 4, p 57**

[132] Act, s 2, 5, 6(5)(b), 6(9), 7 **ABA, Tab 20**

[133] Panel Regulations, s 2(c), **ABA, Tab 21**

most recent version of the consumption data software. A newer version, containing updated data, was released in 2013.[134] As PMRA noted in its Response to NOO, PMRA conducted a dietary exposure analysis to ensure that the new consumption data did not change its assessment of risk. PMRA found that there was no significant difference in food intake patterns or dietary exposure.[135]

75. Moreover, PMRA indicated that the estimated exposure levels for all population subgroups was well below acceptable limits.[136] PMRA further noted that, where a pesticide is registered for multiple uses (e.g. pre-emergent and desiccant uses), the residue level used in DEEM to estimate exposure from all crops of that type would be the highest residue observed among all scenarios tested.[137]

76. As such, exposure was conservatively calculated based on the assumptions that all crops that an individual may consume were treated and all crops were treated in a manner that results in the highest possible residue.[138] It was, therefore, reasonable for PMRA to conclude that this objection did not raise a scientifically founded doubt with respect to the validity of its assessment of glyphosate.

C. PMRA'S REASONS WERE SUFFICIENT

77. The Appellant relies on *Vavilov* to suggest that the reasons offered by PMRA do not adequately reflect the stakes. The principle of responsive justification in reasons, as outlined by the Supreme Court of Canada and referenced by the Appellant, applies where the decision at issue has a significant impact on individual rights. As described in *Vavilov*, these are decisions where the consequences "threaten an

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[134] Pilote Affidavit, paras 53-54, **Appeal Book, Tab 8, pp 1023-1024**

[135] Response to NOO, Comment 4, pp 5-6, **Appeal Book, Tab 4, pp 58-59**; Pilote Affidavit, para 54, **Appeal Book, Tab 8, p 1024**

[136] Response to NOO, Comment 4, pp 5-6, **Appeal Book, Tab 4, pp 58-59; s**ee also: Final Re-evaluation Decision, p 4, **Appeal Book, Tab 31, p 2491**

[137] Response to NOO, Comment 4, p 6, **Appeal Book, Tab 4, p 59**

[138] Response to NOO, Comment 4, p 6, **Appeal Book, Tab 4, p 59**

individual's life, liberty, dignity, or livelihood."[139] The decision of PMRA not to assemble a review panel is not such a case.

78. PMRA's response to the NOO meets the threshold for sufficient and responsive reasons.

79. First, PMRA's discretionary decision not to appoint a panel to review the decision, which comes following a detailed and lengthy scientific review, all of which is summarized in a Proposed, followed by a Final, Re-evaluation Decision – does not engage individual rights or liberties and ought not to attract a requirement to supply rigorous reasons.

80. Second, *Vavilov* recognized that reasons must be assessed in light of the nature of the decision-making body.[140] PMRA is not an adjudicative decision maker, but a specialized agency tasked with applying its scientific expertise in the public interest.

81. Third, *Vavilov* did not displace the law's longstanding recognition that deference is owed to administrative decision makers carrying out duties delegated to them by Parliament. A party seeking to set aside a decision must establish "sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency."[141] The flaws must be central to the decision, and not merely peripheral. Decision makers are not required to include all arguments and details a judge might have preferred.[142]

82. PMRA's response provides clear and transparent reasons outlining why PMRA declined to exercise its discretion to appoint a review panel to assist it in addressing any issue raised in the NOO. That response came following years of

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[139] *Vavilov* at paras 91-98, 133-135, **ABA, Tab 1**

[140] *Vavilov* at paras 91-94, **ABA, Tab 1**

[141] *Vavilov* at para 100, **ABA, Tab 1**; *Canada (Attorney General) v Zalys*, 2020 FCA 81 ["*Zalys*"] at para 5, **ABA, Tab 5**

[142] *Vavilov* at paras 91, 128, **ABA, Tab 1; *Zalys*** at para 5, **ABA, Tab 5**

extensive scientific evaluations by PMRA including public consultations concerning the health and environmental risks of glyphosate. The Appellant may disagree with PMRA's assessment that it did not require the assistance of external expert scientists in relation to its evaluation of the safety of glyphosate but this disagreement does not render PMRA's decision unreasonable. To the extent the Appellant appears to also disagree with the underlying Final Re-evaluation Decision, as Justice Simpson correctly noted, the reasonableness of that decision is not before this Court

D. MANDAMUS IS NOT AN APPROPRIATE REMEDY IN THIS CASE

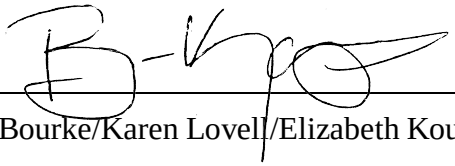
83. In the event PMRA made any reviewable error in exercising its discretion not to appoint a review panel, the Appellant is not entitled to the mandatory order it seeks.[143] The appropriate remedy would be to remit the matter to PMRA for reconsideration having regard to any guidance this Court may provide.[144]

IV. ORDER SOUGHT

84. For all of the foregoing, the Minister of Health asks that the Application be dismissed with costs payable to her.

ALL OF WHICH IS RESPECTFULLY SUBMITTED

Dated at Toronto this 12th day of February, 2021.



Andrea Bourke/Karen Lovell/Elizabeth Koudys

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[143] *Apotex Inc v Canada (Attorney General)* (1993), [1994] 1 FC 742 (Fed CA) at para 45, aff'd [1994] 3 SCR 1100 ("*Apotex*"); *Campbell v Canada (Chief Electoral Officer)*, 2011 FCA 74 at para 126, **AGC-BA, Tab 5**

[144] *Canada (Health) v the Winning Combination Inc*, 2017 FCA 101 at para 58, **AGC-BA, Tab 6**

V. AUTHORITIES

1. *Agraira v Canada*, 2013 SCC 36
2. *Jog v Bank of Montreal*, 2020 FCA 218
3. *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65
4. *Dunsmuir v New Brunswick*, 2008 SCC 9
5. *Entertainment Software Association v Society of Composers, Authors and Music Publishers of Canada*, 2020 FCA 100
6. *David Suzuki Foundation v Canada (Health)*, 2019 FC 1637
7. *N.L.N.U. v. Newfoundland & Labrador (Treasury Board)*, 2011 SCC 62
8. *Wier v Canada (Health)*, 2011 FC 1322
9. *R v Lifchus*, [1997] 3 SCR 320
10. *Canada (Attorney General) v Zalys*, 2020 FCA 81
11. *Apotex Inc v Canada (Attorney General)* (1993), [1994] 1 FC 742 (Fed CA), aff'd [1994] 3 SCR 1100 ("*Apotex*")
12. *Campbell v Canada (Chief Electoral Officer)*, 2011 FCA 74
13. *Canada (Health) v the Winning Combination Inc*, 2017 FCA 101
14. *Merck Frosst Canada Ltd v Canada (Health)*, 2012 SCC 3