Court File No. T-2292-22

FEDERAL COURT

SAFE FOOD MATTERS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

NOTICE OF APPLICATION
Pursuant to section 18.1 of the *Federal Courts Act*

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED by the applicant. The relief claimed by the applicant appears on the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the applicant. The applicant requests that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the Federal Courts Rules and serve it on the applicants' solicitors WITHIN 10 DAYS after being served with this notice of application.

Copies of the Federal Courts Rules information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date: 31-OCT-2022 Issued by: Vanessa George
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APPLICATION

1. This case is about of the refusal of Canada's pest management regulator, the Pest Management Regulatory Agency ("**PMRA**"), to appoint an independent review panel to examine the health risks of pest control products containing glyphosate, the most heavily used pesticide in Canada.

2. The PMRA completed a re-evaluation of glyphosate under the *Pest Control Products Act* ("**Act**") in 2017 approving the registration of glyphosate. In response, Safe Food Matters Inc. filed a notice of objection under section 35 of the Act, requesting that the PMRA appoint an independent review panel to reconsider the decision to approve the registration of glyphosate.

3. The PMRA denied Safe Food Matters Inc.'s objection in 2019. Safe Food Matters Inc. judicially reviewed the PMRA's 2019 decision.

4. On appeal the Federal Court of Appeal held that the PMRA's decision to refuse Safe Food Matters' objection was unreasonable. The Federal Court of Appeal quashed the PMRA's refusal of Safe Food Matters Inc.'s 2017 notice of objection and remitted the matter back to the PMRA for re-determination.

5. The Federal Court of Appeal also provided Guidance to the PMRA on the interpretation of legislative factors, and required the PRMA to explain how it had regard to those factors, when redetermining the issues in order to "avoid a possible 'endless merry-go-round of judicial reviews and subsequent redeterminations'" (the "**Guidance**").

6. On September 29, 2022 the PMRA again refused the objection of Safe Food Matters Inc. (the "**New Decision**"). In making the New Decision the PMRA did not follow the Court's Guidance to have regard to the remittal legislative factors, nor did it communicate how it had regard to those factors.

7. Instead of following the Court's direction to explain how its decision aligned with the legislative factors, the PMRA crafted an entirely new test for responding to notices of objection, without regard to those factors. One of the pillars of the Act is to

"invite public participation in the regulatory scheme", but the new test closes the door on this invitation.

8. The New Decision is unreasonable and procedurally unfair. The Applicant returns to the judicial review "merry-go-round" to require the PMRA to observe the requirements of the Act and, in particular, to ensure the requirement for public participation in the regulatory scheme for pesticides is met.

APPLICATION:

9. The applicant makes application for:

i. A declaration that the test established by PMRA for whether a review panel should be established under section 35(1) of the *Act* and section 3(b) of the *Review Panel Regulations*, and the decision resulting from the application of that test, are both unreasonable, and/or procedurally unfair; and

ii. An order quashing the decision of the PMRA and remitting the matter back to the PMRA with instructions for re-consideration; or

iii. In the alternative, an order quashing the decision of the PMRA and ordering that the PMRA convene a review panel to address the objections of the Applicant.

iv. An order that each party shall bear their own costs, or, in the alternative, an order for costs in favour of the Applicant.

v. Such further and other relief as the Applicant may advise and the court may permit.

THE GROUNDS FOR THE APPLICATION ARE:

The Parties

10. The Minister of Health is responsible for administering the Act. The Minister has delegated this responsibility to the PMRA.

11. The applicant Safe Food Matters Inc. ("**Applicant**" or "**SFM**") is a Canadian non-governmental organization dedicated to promoting public health by working to uphold the administration of laws that are protective concerning inputs to food, including pesticides.

12. The Applicant has public interest standing. It sought judicial review in Federal Court of PMRA's January 11, 2019 decision to reject its notice of objection ("**NoO**") concerning the re-registration of glyphosate, and successfully appealed the Federal Court's decision to the Federal Court of Appeal ("**FCA**").

The Statutory Scheme for Regulation of Pest Control Products in Canada

13. The Act is a protection statute first and foremost. Subsection 4(1) of the Act provides that the "primary" purpose of the Act is the prevention of "unacceptable risks" to people and the environment from the use of pesticides. Acceptable risk is defined in subsection 2(2) of the Act, which provides that "the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration."

14. As stated by the Federal Court of Appel ("**FCA**"), the protective purpose of preventing unacceptable risks to people and the environment is achieved through three pillars of the Act: i) a rigorous, scientifically based approach; ii) a strong re-evaluation process when more is known about the product; and iii) the opportunity for public participation in the regulatory process to enhance decision-making and increase public confidence in it.

Pillar of A Rigorous, Scientifically Based Approach

15. In the instance of both an initial registration (subsection 7(7)(b)) and a re-evaluation (subsection 19(2)(b)), the Minister is to apply a scientifically based approach. The rigorous, scientifically based approach recognizes that pesticides by their nature pose risks and that those seeking the registration of pesticides for use in

Canada (the registrants) have the onus during the evaluation process and thereafter of proving there is a reasonable certainty of no harm to health or the environment arising from the use of pesticides.

16. In applying its scientifically based approach to the assessment of health risks, the Minister is required to consider, among other relevant factors, "information on aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational sources, including drinking water and use in and around homes and schools".

Pillar of A Strong Re-evaluation Process

17. The strong re-evaluation process recognizes that science evolves, and requires that registered pesticides be re-evaluated on a cyclical basis. Since the product has been on the market for well over a decade when it is re-evaluated, more information and reports on its risks and effects would be available. The re-evaluation is to be initiated by PMRA every 15 years and the registrants retain the onus of ensuring the reasonable certainty of "no harm" remains following re-evaluation.

Pillar of Public Participation

18. The public participation pillar of the Act allows the public to participate in decision-making and inform decisions on pesticides, with a view to ensuring the public protection purpose of the Act is met. Section 4(2) of the Act sets out the "ancillary objectives" and *requires* the Minister to

> "2(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" .

The preamble includes this provision which indicates public participation should occur in ways that are consistent with the objectives of the Act:

> 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… (emphasis added)

19. The notice of objection provisions of the Act are set out in sections 35-40 of the Act. They provide the only statutory opportunity for participation by Canadians after a re-evaluation decision has been taken, and also the only opportunity for examining the quality of the risk assessments underlying a re-evaluation decision. The key section is section 35(1), which allows "any person" to file a notice of objection to a decision referred to in paragraph 28(1) (a) or (b), which includes a re-evaluation decision, within 60 days of the decision being made public. "Person" is defined to include an individual and an organization, so registrants and other pesticide organizations can file a notice of objection to the same extent as can individual members of the public.

20. Section 35(3) speaks to establishment of a review panel:

> **Establishment of review panel**
>
> (3) After receiving a notice of objection, 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.

21. Public participation in the review panel process is codified. Section 35(7) indicates a review panel "shall give any person a reasonable opportunity to make representations in respect of the decision under review", and section 35(8) states the review panel hearings shall be open to the public.

Establishment and Role of a Review Panel

22. The *Review Panel Regulations S.O.R./2008-22* ("**Regulations**") in section 3 set out two factors the Minister must consider in determining whether to establish a review panel ("**Review Panel**"):

> **Establishing Review Panels**
>
> 3 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. (emphasis added)

23. The regulatory scheme is clear that the Review Panel is to be fully independent from the PMRA and free from any actual or potential conflict of interest. Section 4 of the Regulations requires that each Review Panel member: not have been employed in federal government, a federal corporation or a Crown corporation for at least a year; provide a written statement that they are free from actual or potential conflict of interest; and undertake to advise of any such conflict of interest that may arise.

24. The Regulations speak to the material that must be submitted with a NoO. Section 2(c) requires a "scientific basis" for the objection, and section 2(d) requires "evidence to support the objection, including scientific reports or test data". Nothing in the Regulations requires new evidence or that evidence meet other specific criteria.

25. The phrase "scientifically founded doubt as to the validity of the evaluations" is not defined or interpreted in the Regulations. However, in 2007 PMRA published a discussion document that sets out PMRA's approach on the criteria it considers when deciding whether to establish a Review Panel. Discussion Document 2007-01 is entitled *"Reconsideration of Decisions under the New Pest Control Products Act*" ("**Discussion Document 2007-01**"). Section 2.1.2 sets out the following criteria to be considered (the **"Reconsideration Criteria"**):

2.1.2 Criteria for Establishing a Review Panel

The decision whether to establish a panel must be made on the merits of the case presented by the objector who filed the notice. In general, the following criteria will be considered in determining whether to establish a panel:

• whether the information in the notice raises doubt as to the **interpretation of the scientific information**, on which the decision was based;

> • whether the information in the notice raises any **disagreements as to the applied methodology** of the scientific information, on which the decision was based;
>
> • whether the information in the notice raises concern(s) as to the **relative weights given to data** impacting on the risk assessment of the scientific information, on which the decision was based;
>
> • whether the information in the notice raises concern(s) regarding the **conclusion reached** during the decision making process;
>
> • whether the advice of one or more expert scientists would be useful and appropriate in responding to the issue(s) identified in the notice; and
>
> • whether the Minister has not already received such above noted advice.
>
> Objections that concern matters of regulatory practice, claim allegations of bias and/or concern an issue on which the PMRA has available recent independent expert opinion would not normally be referred to a panel.

26. Based on the Reconsideration Criteria, an evaluation is not valid if there are concerns with PMRA's interpretation of the evidence, with the methodology it applied, with the weights it accorded to data, or with the conclusion it reached in its evaluation.

The Guidance of the Federal Court of Appeal to PMRA

27. The Federal Court of Appeal provided the Guidance to the PMRA for use in making the re-determination as to whether or not to establish a review panel. The Guidance concerned interpreting the legislation. Justice Rivoalen wrote for the unanimous Court (p.20, 21):

> [65] In determining this matter and, in particular, in going about the interpretation of the legislation, I would suggest that the PMRA should have regard and communicate how it had regard at least to the following:
>
> - The specific text, context and purpose of the preamble of the Act;
> - The definitions of "health risk" and "acceptable risks" in subsections 2(1) and 2(2) of the Act;
> - Consideration of the primary objective of the Act set out in subsection 4(1) of the Act;

- The meaning of "a scientifically based approach" when the PMRA undertakes a re-evaluation of a pest control product as set out in subsection 19(2) of the Act;

- The specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act;

- The specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act;

- The specific threshold to be met when assessing "scientifically founded doubt" pursuant to the factors set out in section 3 of the Regulations;

The criteria that would determine whether the advice of expert scientists would assist in addressing the subject matter of the notice of objection under section 3 of the Regulations. [66] The PMRA should then explain why it has made the decision it has, based on the interpretation of the legislation it has reached and the facts it has found.

The New Decision

28. In September 2022 the PMRA once again rejected the notice of objection of Safe Food Matters Inc. (the "**New Decision**"). In the New Decision the PMRA at the outset recited some but not all of the applicable provisions of the Act, apparently in response to the Guidance of the FCA. It set out the protective purpose of the Act, defined "health risks" and explained "acceptable risk" and set out its approach to assessing pesticides, referencing it as a "science-based approach". The PMRA was highly selective in the way it addressed the applicable provisions of the Act.

29. PMRA described the purpose of a notice of objection narrowly as having the sole purpose of helping the PMRA understand which aspects of its evaluation are objected to. At no time does the PMRA indicate that the purposes of the notice of objection provisions are to enhance public confidence and participation in decision-making and to provide a check to ensure PMRA follows a scientifically based approach in its evaluations.

30. It described the notice of objection process and provisions of the Act, and indicated PMRA is permitted to seek the advice of a review panel "where warranted",

and indicated the role of the review panel was to review the decision and make a recommendation:

> "To this end, the purpose of a Notice of Objection is to identify the aspects of the scientific evaluation supporting the registration or re-evaluation/special review decision to which objection is taken and to request that the scientific aspect in question be referred to an external review panel whose role is to review the decision for the purpose of recommending whether the decision should be confirmed, reversed or varied".

31. In the above passages describing the role of the Review Panel, the PMRA is simply repeating statutory language and not providing more information on the role of the Review Panel or that places the role in the statutory scheme. The mere recital of legislative provisions is not the same as having regard to those provisions in the reasons.

32. It indicated that since objections are filed after a lengthy evaluation and public consultation, "they should be precise in identifying the scientific aspect to which objection is taken and should be well-supported by evidence." PMRA did not provide an explanation of what is meant by "scientific aspect" of the evaluation. PMRA's requirement that objections be well supported by evidence appears to treat the information to be provided in a notice of objection as equivalent to the rigorous science required for an evaluation, an approach that is not supported by the regulatory scheme or statutory wording.

33. PMRA then indicated that if the criteria in section 35(1) of the Act and section 2 of the Regulations are met, the PMRA will review the Notice of Objection to determine whether to establish a Review Panel. It then quoted the provisions of section 3(a) and (b) of the Regulations.

34. Section 3(a) speaks to the information in the notice raising '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" (the "**SFD Factor**"). PMRA did not provide an explanation or definition of "scientifically founded doubt as to the validity of the evaluation" or reference Discussion Document

2007-01. Section 3(b) speaks to "whether the advice of experts scientists would assist in addressing the subject matter of the objection" (the "**Advice Factor**").

35. PMRA then set out a new test. On pages 3 and 4 of the New Decision it set out new criteria that it will consider in "evaluating a notice of objection" ("**Review Panel Criteria**"). PMRA does not explain what it means by "evaluating a notice of objection". The role of PMRA at this stage is not to evaluate a NoO in the way PMRA evaluates the evidence of a registrant in a risk assessment. The role is to ask whether a NoO raises a doubt and whether a panel would assist.

36. Criterion 1 of the new test relates to the SFD Factor, and Criterion 2 relates to the Advice Factor:

1.Does the information in the notice of objection raise a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and value of the pest control product? To assess whether there is scientifically founded doubt, PMRA will consider:

a. Is the scientific basis for the objection directly linked to the evaluation of the pest control product?

b. Was the evidence supporting the objection considered in the evaluation?
   i. Was the information available prior to publishing the decision?
      - If the information was available, was it considered in the assessment?
   ii. If the evidence was not considered, does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product?

c. Does the scientific basis of the objection and the evidence provided in support of the objection, when considered with all scientifically reliable information available and considered by PMRA at the time of the decision, present uncertainty in an aspect of the evaluation.

The above criteria are directed at a science-based review of the objection and will inform whether there may be scientifically-founded doubt raised by the objection concerning an aspect of the evaluation on which the final decision was based.

2. **Would the advice of expert scientists assist in addressing the subject matter of the objection? To assess this question, PMRA will consider:**

a) Is there is a lack of agreement among federal government regulatory scientists with respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?

b) Is the area of science relatively new and the regulatory approach still under development globally and, in this context, does the PMRA believe that the advice of the panel will aid in the regulatory decision-making process?

c) Is there lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?
    i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'
    ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

37. PMRA then proceeded to summarize and provided responses (each, a "**Response**") to each of the objections set out in the NoO.

THE NEW DECISION IS UNREASONABLE AND PROCEDURALLY UNFAIR

38. The New Decision is unreasonable. In particular, in the New Decision:

i. PMRA did not have regard to at least three of the Guidance points directed by PMRA and thereby still fails to interpret the legislation;

ii. PMRA, in its general approach and in its particular Responses, fails to apply its interpretation of the legislation and does not comply with the legislative constraints;

iii. PMRA introduces new criteria for section 3(b) of the *Review Panel Regulations* that*:*

    i. are not justified, intelligible, or rational; and

    ii. do not comply with applicable legislative constraints.

39. The introduction of new criteria for section 3(b) of the *Review Panel* Regulations is not procedurally fair to the Applicant.

I. PMRA Did Not Have Regard to Three Guidance Points and Thereby Still Fails to Interpret the Governing Legislation

40. In its reasons for the New Decision, PMRA did not follow the Guidance of the FCA. It did not speak to how it had regard to least three of the Guidance legislative factors; namely:

i. The fifth factor, namely "the specific role and purpose of a review panel, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under subsection 35(1) of the Act" (the "**Panel vs. PMRA Guidance**");

ii. The sixth factor, namely "the specific role of the PMRA and its tasks to perform when it undertakes a review of a notice of objection pursuant to subsection 35(3) of the Act" (the "**PMRA Role Guidance**"); and

iii. The seventh factor, namely "the specific threshold to be met when assessing "scientifically founded doubt" pursuant to the factors set out in section 3 of the Regulations (the "**SFD Threshold Guidance**").

41. The approach of PMRA to at least three Guidance factors of the FCA makes it clear that PMRA does not see a role for a review panel in the way it interprets the Act. On its interpretation, the key power for all decision-making on a notice of objection rests with the PMRA only. This does not accord with the text, context or purpose of the Act, which sees a role for both a review panel and objectors in ensuring the protective purpose of the Act is met**.**

42. *Panel vs. PMRA Guidance*. First, PMRA does not explain how its role and purpose with regard to review of a notice of objection *contrasts* with that of a review panel, even though the FCA required such an explanation in its Panel vs. PMRA Guidance. In PMRA's own words, the possibility of the PMRA seeking the advice of a review panel would occur only "if warranted", but it provides no guidance on what would "warrant" such advice. When describing the purpose of a notice of objection, PMRA purports to speak to the role of the review panel, but states only that its role is to review the decision and make a recommendation. This description provides no

legislative interpretation, since this "review" role is what is explicit in the legislation, and it provides no "contrast" discussion.

43. The PMRA does not provide a "contrast" discussion because in its interpretation of the legislation, all decision-making on a notice of objection rests with the PMRA. It is only in the most remote circumstances that the possibility of seeking the advice of a review panel even exists. In PMRA's scheme of the 3-part Advice Factor Criterion 2 tests for whether a review panel might be established, all information relevant to the test is within the control and knowledge of the PMRA, not a member of the public. A member of the public would not have knowledge of the first and third legs of the test. It would not know, or could it know, if there is "lack of agreement among federal regulatory authorities" with respect to the evidence presented. It would not know, at least not without extensive research, whether "there is lack of uniformity in global regulatory evaluations". On the second leg of the test, even if a member of the public could show that the "area of science is relatively new and the regulatory approach under development", PMRA still has control because, in its own words, PMRA has to "believe" that the advice of a panel would aid in the regulatory decision-making process. The test does not set out the requirement for showing a basis for such "belief".

44. The PMRA treats the submission of a notice of objections as just a submission of more evidence toward the re-evaluation that is to be treated as re-evaluation evidence and assessed by PMRA as re-evaluation evidence. On the issues of whether a review panel could assist, the PMRA assigns to itself the task of re-weighing any new evidence.

45. In this regard, PMRA unreasonably requires that the objector provide new evidence and that this evidence be of the same scientific standard required of the registrant. In essence, the SFD factor requires the objector to provide new evidence that proves that harm to human health or the environment, when weighed against all of the evidence already considered in the re-evaluation, is likely, in order to raise a scientifically founded doubt. The test requires the submission of new evaluation evidence.

46. The PMRA does not explain how requiring objectors to provide new evidence meeting the standard of meet the criteria for "scientific acceptability for use in the evaluation of a pest control product" is consistent with the statutory onus placed on the registrant, not an objector, for proving "acceptable risk". Similarly, PMRA places such evidence in the context of all "scientifically reliable" information available and considered by PMRA in its evaluation. "Scientifically reliable" information is defined with reference to *Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments*, which assigns to the PMRA – and not the independent review panel – the task of reconsidering the PMRA's re-evaluation decision.

47. The PMRA does not explain why Parliament created an independent review panel process for reconsideration of decisions under section 35 of the Act if the intent of section 35 was for the PMRA to merely reconsider its own decisions. Fundamentally, the PMRA treats the exercise of its discretion to appoint a review panel as an opportunity to itself reconsider the underlying re-evaluation decision, and re-weigh the evidence already reviewed along with new evidence of the objector against the standards of the evaluation decision.

48. *PMRA Role Guidance*. Because PMRA treats NoO evidence as re-evaluation evidence, it cannot explain how its approach to a NoO is different than its approach to a re-evaluation. The PMRA Role Guidance of the Federal Court of Appeal called for an explanation of PMRA's approach to a NoO, but PMRA states only that "the PMRA review a Notice of Objection to determine whether to establish a review panel" if the criteria the Act and section 2 of the Regulations are met. Again, this does not provide any interpretation of the legislation, but rather just repeats the requirements of the legislation.

49. *SFD Threshold Guidance*. The FCA required an interpretation of the "specific threshold to be met when assessing 'scientifically founded doubt' pursuant to the factors set out in section 3 of the Regulations". At issue before the FCA was the evidentiary threshold to be met when "raising a doubt", whether an objector had to provide any new evidence, whether that evidence had to be peer-reviewed and whether there was an onus on the objector to prove that harm was likely with new evidence.

Understood in context, the FCA sought that the PMRA provide clarity for objectors on the onus they had to meet to establish a scientifically founded doubt and how that onus accorded with the Act's scheme and interpretation, which scheme and wording provides for a different evidentiary onus on the registrant to prove acceptable risk.

50. The PMRA provides no clarity or explanation of "threshold" in framing its criteria or reciting selected portions of the legislative framework. However the criteria for the SFD Factor are strongly suggestive of a requirement for the objector to provide new evidence showing that harm is likely, a point argued against at the FCA.

51. The PMRA provides no explanation of the word "doubt" in this context, even though the requirement to raise a "scientifically founded doubt" contrasts with the wording and standard of certainty applied in the "reasonable certainty of no harm" test of the Act that applies to re-evaluation evidence. It also provides no explanation of the phrase "validity of the evaluations", nor clarity for objectors about what level of evidence would be required to question this, but instead indicates that the target of the inquiry is on an "aspect of the evaluation".

52. This is despite the fact that the record, particularly the Memorandum of Fact and Law ("**Factum**") of SFM and the Interveners in the Federal Court of Appeal, spent a great many pages discussing the meaning and threshold for "doubt" and "validity of the evaluations." The FCA, in requiring an explanation on the threshold, was requiring clarity on the threshold of "doubt" as it applies to whether the evaluation was valid. The PMRA's reasons are unintelligible in this regard.

II. *PMRA Fails to Apply its Interpretation of the Legislation and Did Not Comply with Legislative Constraints*

53. The PMRA did not explain in the initial pages of the New Decision or in the specific responses it provided to the objections ("**Responses**") why it made the decisions it did with respect to each objection based on its interpretation of the legislation. In did not provide any explanation that showed how or even explained that

the Responses complied with the legislative constraint of its interpretation of the Act and Regulations.

54. In the initial pages, PMRA simply recites selected provisions of the Act. However, the mere recital of legislative provisions is not the same as having regard to those provisions in the reasons.

55. In each particular Response the PMRA provided to the objections, the PMRA did not reference its interpretation of the legislation or explain how the Response accorded with the legislation. No reasons were provided that showed how or even that the particular Response complied with the legislative constraint of PMRA's interpretation of the Act and Regulations. PMRA also failed, in its Responses, to grapple with the issues raised in the objections or place them within the legislative constraints of the Act.

56. The Applicant presented 9 objections to the 2017 re-registration decision taken by PMRA to renew the registration of glyphosate for another 15 plus years. The objections and approach of PMRA to them were not justified, intelligible or rational, and did not accord with the applicable legislative constraints. These points are made in the discussion on some of the objections presented below, with the objections presented in an order that differs than the order set out in the NoO.

Objection 9: Reduction of Safety Factor Without Valid Scientific Data

57. In the NoO, the Applicant objected that the Act requires the application of a margin of safety, if glyphosate is used in or around homes or schools, that is ten times greater than the margin of safety that would otherwise be applicable, unless the Minster determines "on the basis of reliable scientific data" that a different margin of safety would be appropriate.

58. Safe Food Matters in its NoO indicated that in the consideration of prenatal or postnatal toxicity, PMRA had found an increased incidence of fetal cardiovascular malformation in a rabbit developmental toxicity study, and that PMRA considered this a 'serious endpoint'. PMRA nevertheless reduced the safety factor from 10 to 3

in this instance, indicating the "concern regarding the serious nature of this effects was tempered by the presence of maternal toxicity at the same and lower dose levels in this study". The Applicant argued that the tempering of the concern, and the reduction of the safety factor, was not permitted based on the approach outlined in Science Policy Note (SPN2008-01): *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides* ("**SPN2008-01**").

59. In its Response, PMRA stated merely that "the rationale for the PMRA's choice of safety factors was provided in PRVD2015-01 (page 17) and RVD2017-01 (page 27-28)". In other words, it just pointed to the re-evaluation documents for its explanation, but did not provide any reasoning to show how this explanation aligned with the purposes of the legislation. The rationale set out in PRVD2015-01 was that the fetal cardiovascular malformations was considered a serious endpoint, "[h]owever the concern regarding the serious nature of this effect was tempered by the presence of maternal toxicity at the same and lower dose levels" and therefore the Pest Control Products Act factor was reduced to thee-fold. The discussion in RVD2017-01 just pointed to the discussion in PRVD2015-01.

60. The primary purpose of protection of Canadians from the harms of pesticides, as it relates to protection of infants and children, is best served by preservation of the 10-fold safety factor for infants and children. Not only does the Act make this clear, but so does SPN 2008-01. The text, context and purpose of the relevant provisions show that protection of infants and children is of fundamental importance in the legislative scheme. The Act in section 19(2) is explicit that the Minister must consider potential pre- and post-natal toxicity and completeness the data on toxicity and exposure to infants and children. The wording in the section is clear that "reliable scientific data" is required if a reduction in the safety factor is even to be considered. The preamble to the Act indicates that in assessing risks to individuals, consideration should be given to the different sensitivities to pest control products of infants and children, among others.

61. The wording in SPN2008-01 strongly supports the application of the 10-fold safety factor, also called the "**PCPA Factor**" by PMRA. It provides for the "presumptive application of the 10-fold factor for the protection of infants and children. In other words, the onus is on the PMRA to provide a reliable scientific rationale in those cases where the 10-fold PCPA factor is reduced."

62. PMRA in its Response did not explain how reducing the factor to 3 was protective to children or how it met the Act's objectives. It just said that it was allowed to do so based on "contextual information". It indicated that assessing harm to maternal health will overlap with the assessment of fetal toxicity, and that "[d]ecreased body weight or body weight gain at sensitive stages of development can result in change in the fetus *independent of direct chemical harm* to the fetus." (emphasis added)

63. The PMRA's recourse to contextual information is not rational, justified or intelligible in light of the record before the PMRA. Based on the facts set out in the record, the criteria set out in SPN2008-01 for reducing the safety factor were not met, but PMRA misapprehended or ignored this evidence.

Objections 1 and 2: Spraying Glyphosate on Crops Pre-Harvest and Associated Risks

64. In its first objection, Safe Food Matters pointed out PMRA's own statement in RVD2017-01 that glyphosate is registered as a desiccant on a number of conventional crops. PMRA stated in RVD2017-01 (at 38) that:

> "Glyphosate is registered for pre-harvest use (desiccation) on a number of conventional crops including wheat, barley, oats, canola, flax, lentils, peas, dry beans, and soybeans".

Safe Food Matters then explained in its NoO that when glyphosate is applied to crops, the chemical moves to the seed of the plant, which people eat, by a process called "translocation". It explained that when glyphosate is applied to a crop that is not physiologically mature, it accumulates more in the seed. Safe Food Matters then pointed out that high levels of residue had been observed in cereal and legume crops, and provided referenced studies in support.

65. Safe Food Matters then moved to bolster its point that high levels of residue were being found in seeds by pointing to the fact that exceedances of maximum residue limits ("**MRLs**") were occurring in some crops. In Objection 2, SFM pointed out that the re-evaluation decision did not contain a discussion of pre-harvest desiccation or discuss the associated risks that might arise from it. "It would appear that an examination of the risks arising from dietary exposure to crops that have been desiccated with glyphosate was not part of the Re-evaluation".

66. The approach of Health Canada to pesticide decision making is based on the document referenced by PMRA in its Response, entitled *Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks* ("**Framework**"). As discussed in the Factum of the Appellant at the FCA (paras. 70-72), issue identification is the first step in the Framework, and part of that first step is "identifying the mode and mechanism of action of the agent". In its re-evaluation, PMRA did not identify translocation as a mode or mechanism of action of the agent, nor identify the risk of high levels of glyphosate accumulating in seeds by virtue of translocation.

67. In its Response, the PMRA failed to comply with or apply the Framework. The PMRA failed to identify the mode and mechanism action of the agent as translocation and failed to identify the risk of high levels of glyphosate accumulating in seeds eaten by Canadians. The PMRA then went on to make a distinction not supported in the record between desiccation and pre-harvest use. In this regard the PMRA misapprehended the evidence before it in a fundamental way, and unreasonably failed to follow its own policies without a rational, intelligible explanation for doing so.

Objection 3: PMRA Used Outdated Consumption Data and Did Not Assess Increased Consumption

68. Safe Food Matters objected that the dietary exposure assessment conducted by PMRA was based on data taken from 1994-1996 and 1998 on what Americans ate. Safe Food Matters indicated that consumption of relevant crops had increased dramatically since that time, and that even if PMRA used more recent data to which it had access, taken from at best 2010, this data was still inadequate because it did not take into account the evidence presented of increased consumption of relevant crops. It contended that that a valid evaluation would have assessed current levels of consumption that accounted for such increased consumption.

69. PMRA's Response defended the use of this out of date consumption data without explaining how this was consistent with the scientifically based approach, the protective purposes of the Act or the Framework.

70. The PMRA further concluded that updating the consumption data was not expected to affect the outcome of the health risk assessment. In support of this conclusion, PMRA provided a footnote indicating an updated dietary assessment was conducted for glyphosate as part of the assessment for proposed maximum residue limits set out in Proposed Maximum Residues Limit PMRL2021-10.

71. Safe Food Matters provided comments to PMRL 2021-10 to PMRA on April 13, 2022 ("**PMRL Comments**") that spoke to issues raised in its NoO. Such information was therefore before the PMRA when it issued the September 29, 2022 New Decision and forms part of the record. In the PMRL Comments, SFM provided evidence that consumption data that was more current than that used by PMRA in the dietary risk assessment of glyphosate was available to it at the time of publication of its final decision, but PMRA did not use such data. It also showed the data was Canadian, not American, and so more relevant to assessing risks to Canadians. It showed that the reasons provided by PMRA for its adoption of the US consumption data and the US model were not supportable.

72. The notice of objection evidence before the PMRA also showed there had been a significant increase in consumption in relevant crops since even 2010. The PMRA did not take issue with the evidence, but dismissed the objection. It stated "While PMRA acknowledges the increase of production and consumption of pulses since 2010, this increase is *not expected to result in dietary risks of concern* (i.e., risks above 100% ADI or 100% ARfD)" from glyphosate for two reasons. (emphasis added)

73. The first reason was "no food commodity from the pulse group contributed more than 1% of the total exposure for any population subgroup", and even if the consumption increased substantially, the assumptions in the dietary exposure assessment are very conservative. PMRA comes to the conclusion that there are no risks of concern, without actually having modeled the dietary exposure based on the best evidence available. Reliance on assumptions to avoid employing an evidence-based approach is not a "scientifically based approach". The PMRA's Responses are unreasonable and unintelligible in this regard.

74. The second reason provided by PMRA for dismissing Objection 3 was it indicated that the dietary exposure estimates reported n PRVD2015-01 were "well below the ADI, as well as the ARfD: 20-70% of the ADI and 12-45% of the ARfD for all population subgroups" so a "considerable portion of the reference values remains 'available' before any exposure concerns would be identified".

75. The PMRA fundamentally misapprehended the evidence before it and did not apply its own policies that outlined the scientifically based approach to conducting dietary exposure assessments. There was evidence before the PMRA that the acute reference dose was exceeded in children 1-2 years in the dietary risk assessments for both the glyphosate re-evaluation decision and PMRL 2021-10. Under the PMRA's own policies such exceedances are equated with risks of concern. The PMRA's Response fails to explain how the exceedances did not equate to unacceptable dietary risk, did not explain how it employed a "scientifically-based approach" in accordance with its own dietary risk assessment policies, nor did it explain how this approach accords with provisions of the Act directed at applying additional safety factors and precautions for children and infants.

Objection 5: Label Amendments Don't Address the Risk of Indeterminate Crops

76. Safe Food Matters objected that labels do not mitigate the risks associated with indeterminate crops that are always producing seeds. Labels that prescribe a time to spray based on low moisture content of the seed cannot mitigate risks associated with indeterminate crops because these crops are continually producing seeds, which means there will always be greener, more wet material in the plant that accumulate glyphosate.

77. The risk that indeterminate crops will attract high levels of glyphosate that cannot be mitigated by labels was no not discussed in the evaluation. In the Response to Objection 5 set out in the New Decision, PMRA acknowledges the risk but then provides market reasons, unsupported by evidence or authority, for why it considers the risk to not be of concern.

78. PMRA also assumes that this risk is known by growers and they will decide to not apply glyphosate when grain moisture is greater than 30%, even though use on indeterminate crops has been registered by PMRA, "since incorrect timing of pre-harvest herbicides can … as mentioned by the objector, result in more herbicide residue in the seed". PMRA does not grapple with the fact that growers would not know of the risk because it is not described on labels, nor with the fact that it is the nature of indeterminate crops to always have a quantity of the seeds with grain moisture greater than 30% . PMRA's reasons are not justified, rational or intelligible.

III. PMRA Introduces Criteria for Section 3 of the Review Panel Regulations that are Not Justified, Intelligible, or Rational and that do Not Comply with Applicable Constraints.

79. The reasons of the PMRA on the substance of the new test of the Review Panel Criteria, and how these are applied in practice are unintelligible. It is not clear how the new tests fit together and the "waterfall" of the tests cannot be discerned. It is not clear if the tests are conjunctive or disjunctive. It is not clear what the consequences and next steps are for the answers to the questions asked. The PMRA

does not explain if the criteria for the SFD Factor are to be weighed in a discretionary manner or, if so, which of these criteria get more weight. The PMRA does not explain if all tests must be met or if a Review Panel could be granted where only some are met.

80. With respect to the SFD Factor, PRMA does not provide an explanation of "scientifically founded doubt as to the validity of the evaluations", as mentioned. It indicates that the three criteria in Criterion 1 "will inform whether there may be a scientifically founded doubt raised by the objection concerning an aspect of the evaluation on which the final decision was based". The most that can be gleaned from these PMRA statements is that "scientifically founded doubt" requires "uncertainty", and the "uncertainty" is to be related to an aspect of the evaluation. It appears that in crafting the new test, the inquiry of the PMRA is the same inquiry it asks itself when conducting an evaluation. This is not the test the regulatory scheme requires for a NoO.

81. The PMRA does not explain how a requirement of presenting an uncertainty relates to establishing a scientifically founded doubt. The PMRA equates uncertainty with doubt although the Regulations appear to require something less than proof of uncertainty. The PMRA does not establish the standard of proof that an objector must meet in presenting an uncertainty.

82. PMRA introduces new standards for objection evidence that are overly narrow, such as "criteria for scientific acceptability for use" and "scientifically reliable information". It introduces the standards that, pursuant to policy, relate to laboratory studies without justifying their use on objection evidence. Under the regulatory scheme, laboratory studies are part of the "battery of tests" to be provided by the registrant and are to meet "stringent criteria". The application of stringent laboratory standards to objection evidence is not intelligible.

83. Objection evidence differs from evaluation evidence. Objection information is to be held to a standard of raising a doubt which is lower than that required of "scientifically reliable" evidence, it speaks to the "validity of the evaluation" rather

than whether there is "certainty of no harm", it encompasses information on how evidence is to be interpreted and the weight, methodology and conclusion of an evaluation rather than requiring adherence to stringent guidelines for laboratory studies. In the Review Panel Criteria, PMRA is holding objection information to the standards of, and treating it as, evaluation evidence.

84. PMRA provides no explanation of how the Review Panel Criteria relate to the Reconsideration Criteria set out in Discussion Document 2007-01, which criteria the record shows were previously used and relied upon by PMRA. While the Guidance required that the PMRA describe the test in more detail and justify how the test accorded with the applicable provisions of the Act, it did not provide a *carte blanche* for the PMRA to ignore Discussio Document 2007 -01 or to measure the objection by entirely new standards and criteria without advising the objector or providing the objector an opportunity to respond. The PMRA's New Decision does not explain, in a justified, rational or intelligible manner whether or why the PMRA abandoned the criteria in Discussion Document 2007-01 and developed entirely new criteria, nor why it provided no opportunity for the objector to address the new criteria.

85. As discussed above with reference to the "Panel vs. PMRA Guidance" point, PMRA does not provide an interpretation on the role of the Review Panel in the statutory scheme. PMRA crafts the Review Panel Criteria such that the key knowledge for answering the tests rests with the PMRA only. The Criterion 2 a) question of the agreement of federal scientists on the evidence is not relevant in the regulatory scheme, which sees the evaluation role of PMRA ending once the final decision is published, but PMRA inserts the step of requiring federal scientists who were not involved in the original evaluation to review the NoO. In implementing such a step, PMRA keeps the "independent" review internal to PMRA.

86. Similarly, the Criterion 2a) test asks whether the evidence could "affect the outcome of the evaluation". This establishes a test that is subjective to PMRA; since only the PMRA has the knowledge and control of the evaluation, only it can speak to whether the outcome might be affected. The Criterion allows PMRA to conclude that the outcome would be affected without actually conducting an assessment of the

information presented, which is not contemplated in the scheme and does not accord with the protective purposes of the Act or the pillar of a strong re-evaluation process. A test that is subjective to PMRA is also set out in Criterion 2b), when it asks "does the PMRA believe" that the advice of the panel would assist.

87. The PMRA does not explain with justifiable or intelligible reasons how the particular Review Panel Criteria further the Act's primary purpose of preventing unacceptable risks or the ancillary purpose of enhancing public participation. The PMRA's decision fails to situate the new objection test within the Act's purposes or the legislative scheme with respect to reconsiderations in the Act. The new test does not acknowledge that the notice of objection provisions of the Act serve a protective and public participation role in the regulatory scheme and that this role differs from the purpose, role and participants involved in an evaluation.

88. The general inquiry of the Criterion 2 Advice Factor test is, in essence, an inquiry into the state of the global approach to regulatory decision-making and evaluations and the extent to which PMRA's regulatory framework aligns with the global approach. It is an inquiry into approach on evaluations of pesticide products in general, rather than an inquiry into the specific risks raised that are the subject matter of an objection. In this regard it is not even directed at preventing unacceptable risks and does not further the primary purpose of the Act.

89. The Review Panel Criteria thwart public participation. Since the criteria are crafted such that they are subjective to PMRA or the key knowledge for answering the tests rests with the PMRA, the public cannot make the case for establishing a Review Panel.

90. In addition, the Review Panel Criteria are written in such a way that the possibility of a Review Panel being appointed is very remote. On a generous reading, there is a very narrow set of circumstance that could possibly allow for establishment of a Review Panel. The regulatory area of science has to be new, the evidence has to meet standards for acceptability that are applicable to laboratory studies, there has to be disagreement among federal scientists on the particular evidence presented in the

objection, and also a lack of consensus globally on the regulatory approach to evaluations to the pest control product that is relevant to the Canadian context. PMRA then qualifies the possibility of the occurrence of these circumstances by adding a subjective component to the test – that PMRA "believes" advice was assist, and PMRA considers that the outcome of the evaluation would be affected.

91. Because the set of circumstances are very narrow and remote, and because the knowledge for answering the questions rests largely with the PMRA, the Review Panel Criteria set up a notice of objection regime that is onerous to meet. Moreover, given the elements of the tests that are subjective to PMRA, and the fact that the knowledge to meet the tests rests in large part with the PMRA, and the fact that an objector has only 60 days to bring evidence to the PMRA with respect to the tests, the Review Panel Criteria in effect will thwart all public participation in the objection process.

92. In its application of the Review Panel Criteria to the NoO, PMRA in some instances does not follow the analysis it has prescribed, such that the particular Responses provided are not rational based even on PMRA's own tests. In application of the tests, PMRA also does not provide evidence or support for its conclusions, particularly concerning the global regulatory approach, and accordingly does not provide the public justification required of its reasons.

The Introduction of the Review Panel Criteria is Procedurally Unfair

93. By identifying and applying the new test of the Review Panel Criteria for considering objections the PMRA denied the Applicant procedural fairness insofar as the applicant could not be aware of the case it had to meet. As an objector, the applicant was entitled to proceed on the basis of section 3 of the Regulations and to consider Discussion Document 2007-01 as PMRA's discussion with respect to interpreting the Regulations. In this case however the New Decision effectively supplemented the Regulations by identifying and applying a new test. PMRA did not give the Applicant notice of the new test or seek public comment on the new test. The Applicant first heard of the new test when it received the New Decision. It is

fundamental to procedural fairness that a party seeking the exercise of a statutory power knows what case it has to meet. The PMRA deprived the applicant of that opportunity by adopting and applying a new test without notice and as a result denied the Applicant procedural fairness.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

94. An affidavit from a representative of the Applicant, to be served;

95. Material Requested pursuant to Rule 317 and produced to the Applicant and to the Court pursuant to Rule 318 of the *Federal Court Rules*; and

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

Rule 317 Request

97. The Applicants request that the Minister send a certified copy of the following material not in the Applicant's possession, but in the possession of the Minister, or the PMRA as the Minister's delegate, to the Applicant and to the Registry:

i. All documents in the possession of the Minister, or the PMRA as the Minister's delegate, related to the New Decision including but not limited to:

    i. All briefing notes, memos, monographs and draft briefing notes prepared by PMRA scientific staff setting out the scientific evidence relied on for the New Decision;

    ii. All agendas and minutes of decision in relation to the New Decision;

    iii. All PMRA policies, guidance or practices relied on in the New Decision;

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

Date: October 31, 2022.

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