Court File No.: T-2292-22

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

MOTION RECORD OF THE RESPONDENTS
(motion returnable June 13, 2023 at 9:30am PST)

June 8, 2023

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TO:

FEDERAL COURT OF CANDA
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AND TO:

GRATL AND COMPANY
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Court File No.: T-2292-22

FEDERAL COURT

BETWEEN:

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RESPONDING MOTION RECORD INDEX

TAB 1

Court File No.: T-2292-22

FEDERAL COURT

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SAFE FOOD MATTERS INC.

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- and -

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Respondents

AFFIDAVIT OF EZEL AYDONER
SWORN MAY 18, 2023

I, **Ezel Aydoner**, of the City of Guelph, in the Province of Ontario, **AFFIRM THAT**

1. I am employed as a legal assistant in the Ontario Regional Office of the Department of Justice, which is counsel to the Respondents in this matter, the Attorney General of Canada and Minister of Health. I make this Affidavit in support of the Respondents' response to the motion of the Applicant, Safe Food Matters Inc., seeking transmission of a supplementary certified tribunal record ("CTR") pursuant to Rule 317 of the *Federal Courts Rules* ("*Rules*"). I am informed by Walter Kravchuk, lawyer with the Department of Justice, and believe the following statements to be true.

Background

2. In February 2022, the Federal Court of Appeal ("FCA") quashed a decision of the Pest Management Regulatory Agency (**"PMRA"**) concerning registration of the pesticide glyphosate and remitted the matter for reconsideration (FCA File No.: A-85-20). A copy of the FCA's decision is attached as **Exhibit "A"**.

3. On September 29, 2022, the PMRA made its redetermination decision, attached as **Exhibit "B"**.

Current JR Application

4. On October 31, 2022, the Applicant commenced the present application for judicial review, alleging that the PMRA's redetermination decision was unreasonable and procedurally unfair.

5. On December 15, 2022, the PMRA transmitted the two-volume CTR to the Applicant.

6. On December 20, 2022, the Applicant provided a draft amended Notice of Application ("ANOA") to the Respondents by email dated December 20, 2022, attached as **Exhibit "C"**.

7. By order of Associate Judge Coughlan dated January 20, 2023, the Applicant received leave to serve and file the ANOA, which was served on the Respondents by email dated March 10, 2023, attached as **Exhibit "D"**.

8. It came to the Respondents' attention that, through inadvertence, intended redactions on the basis of irrelevance and solicitor-client privilege were not applied throughout volume 2 of the CTR prior to transmission. Accordingly, the Respondents requested the Applicant's consent to re-file volume 2 of the CTR with the intended redactions applied by letter dated January 30, 2023, attached as **Exhibit "E"**.

Parties Request Case Management

9. Counsel for the Applicant initially refused this request and intimated that the two-volume package transmitted by the PMRA was incomplete. With the consent of the Applicant, the Respondents sought for the matter to be case-managed by letter to the Court dated February 10, 2023, attached as **Exhibit "F"**.

10. By Order of Associate Judge Horne dated February 10, 2023, attached as **Exhibit "G"**, the matter was referred to the Office of the Chief Justice for appointment of a case management judge.

11. By Order of Chief Justice Crampton dated February 21, 2023, attached as **Exhibit "H"**, Associate Judge Duchesne was assigned as the Case Management Judge.

Applicant Requests Supplementary CTR

12. By letter to the Court dated March 10, 2023, attached as **Exhibit "I"**, counsel for the Applicant provided a status update of the proceeding, which included the parties' agreement in respect of volume 2 of the CTR. The Applicant agreed to delete documents over which the Respondents claimed privilege. Conversely, the Respondents agreed that third-party information previously intended for redaction on the basis of irrelevance would be disclosed. In addition, counsel for the Applicant advised of the Applicant's intention to ask the Respondents to supplement the CTR under Rule 317 of the *Rules* and that a group of environmental non-governmental organizations may wish to apply for intervener status.

13. By letter to the Court dated March 14, 2023, attached as **Exhibit "J"**, the Respondents indicated they objected to the Applicant's request for additional documents.

14. On March 20, 2023, the parties attended a case management conference before Associate Judge Duchesne.

15. By Order dated March 21, 2023, attached as **Exhibit "K"**, Associate Judge Duchesne (a) required the Respondents to inform, pursuant to Rule 318(2) of the *Rules*, of their reasons for objecting to the Applicant's request under Rule 317 for a supplementary CTR; (b) set a timetable in relation to a motion to determine the Respondents' objection; and (c) ordered that any interveners may serve and file their motion record for leave to intervene pursuant to Rule 109 of the *Rules* by April 21, 2023.

Applicant Formalizes Request for Supplementary CTR

16. By letter to the Respondents dated March 22, 2023 ("the Rule 317 Request Letter"), attached as **Exhibit "L"**, counsel for the Applicant formalized the basis for the Applicant's request under Rule 317 as follows:

…

1) There are no records of the communications or documents generated by the so-called "Tiger Team" that were assigned to deal with the PMRA's interpretation of its enabling statute. I would expect numerous emails and draft briefing notes and memoranda. The members of the "Tiger Team" are not legal counsel. The interpretation of PMRA's enabling statue [*sic*] is at the core of this judicial review;

2) There are no records dealing with PMRA's interpretation of the significance of the "Monsanto Papers", although the materials disclosed show that PMRA communicated internally about these papers and generated analyses of these papers. These papers are important because they address the need for transparency and independence, and the public perception thereof, in respect of the role of the PMRA and the need for an independent review panel to ensure transparency, accountability and the public perception thereof. The PMRA's ability and willingness to address the distortions of science (ie. ghostwriting, data manipulation, undisclosed conflicts of interest) evidenced in those documents and the non-independent relationships between Monsanto and glyphosate-related lobby and research group disclosed by those documents is relevant to this judicial review.

3) The redactions of the glyphosate reports under Volume 1, Tab 40 and Tab 42, appear on their face to be overbroad. The names of report authors, among other things, appear to be redacted. The claimed basis for the redactions of Tab 40 is "confidential data". The claimed basis for the redactions of Tab 42 is "confidential". I ask that counsel conduct a review of these redactions. I know of no legal basis for redacting the names of the authors of the studies.

4) Documents dealing with PMRA's review of 5 studies in Dr. Portier's letter to EFSA are not included in the materials. I would expect that PMRA has a copy of Dr. Portier's letter to EFSA, internal communications dealing with these five studies and Dr. Portier's letter, and the EPA and EFSA reviews of the studies. Vol.1, tab 45 sets out a powerpoint presentation apparently given by Kimberly Low which implies the existence of many documents dealing with Dr. Portier's letter. I refer you to documents at Vol.1, p.1504, and p.1509 of the record at page 8.

5) Documents dealing with PMRA contact with Monsanto representatives, including Croplife, dealing with glyphosate. The lobby registry refers to many contacts between Croplife (Monsanto's agent) and Manon Bombardier (ADM, PMRA Transformation), Peter Brander (PMRA Executive Director), Frederic Bissonette (PMRA Chief Registrar), Richard Aucoin (PMRA Executive Director), and others within PRMA [*sic*]. Any communications between PMRA and Croplife and/or Monsanto employees or lobbyists that deal with glyphosate should form part of the record.

…

Respondents' Position Regarding Supplementary CTR Request

17. Further to the March 21, 2023 Order of Associate Judge Duchesne, the Respondents outlined their objections to the requested documents under Rule 318(2). By letter dated March 24, 2023, attached as **Exhibit "M"**, the Respondents stated that (a) items #2, 4, and 5 from the Rule 317 Request Letter were irrelevant to the PMRA decision impugned in the

ANOA; (b) the position, scope, and basis of their objection to item #1 was being reconsidered; and (c) the names of the studies' authors mentioned in item #3 would be provided.

18. By letter dated March 27, 2023, attached as **Exhibit "N"**, the 'amended' volume 2 of the CTR — with agreed-upon redactions applied — was transmitted to the Applicant. By Direction of Associate Judge Duchesne dated April 11, 2023, attached as **Exhibit "O"**, the Court confirmed that the 'amended' volume 2 of the CTR can be accepted by the Registry.

19. Over an exchange of emails between March 30, 2023 and April 11, 2023, attached as **Exhibit "P"**, the Respondents clarified their objections to the requested items #1 and #3 of the Rule 317 Request Letter. By email dated March 30, 2023, the Respondents objected to item #1 on the grounds of irrelevance and privilege but advised that, as review of these communications and documents was continuing, the Applicant would be notified if this position were to change.

20. Regarding item #3, the Respondents provided the names of the study's authors but maintained redactions on the basis of Confidential Business Information ("CBI") and Confidential Test Data ("CTD"). The Respondents further advised that CBI and CTD privilege had been claimed in the earlier judicial review application (i.e. FCA File No.: A-85-20) and was not challenged by the Applicant's previous counsel.

21. By letter dated April 14, 2023, attached as **Exhibit "Q"**, volume 3 of the CTR — consisting of documents in respect of item #1 of the Rule 317 Request Letter — was transmitted to the Applicant. By Direction of Associate Judge Duchesne dated May 8, 2023, attached as **Exhibit "R"**, the Court confirmed that volume 3 of the CTR can be accepted by the Registry.

22. By email dated April 21, 2023, attached as **Exhibit "S"**, the Applicant served the Respondents with four affidavits in support of its Rule 317 motion for supplementary documents.

Interveners; Registry of Lobbyists

23. By email dated April 21, 2023, attached as **Exhibit "T"**, the proposed interveners, Environmental Defence Canada Inc. and Friends of the Earth Canada, served the Respondents with their motion record seeking leave to intervene in this application.

24. On May 18, 2023, Walter Kravchuk, lawyer with the Department of Justice, accessed the Government of Canada's Registry of Lobbyists website at http://lobbycanada.gc.ca/en and searched for the Applicant, for the above-named proposed interveners, and for other non-governmental organizations. The said lawyer put together a chart of his findings, copy of which is attached as **Exhibit "U"**.

25. I affirm this affidavit in support of the Respondents' response to the motion of the Applicant returnable June 13, 2023, and for no other or improper purpose.

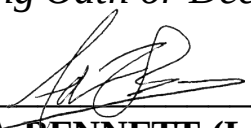
AFFIRMED remotely by Ezel Aydoner in the City of Guelph, before me at the City of Toronto, in the Province of Ontario, on May 18, 2023, in accordance with O. Reg. 431/20, Administering Oath of Declaration Remotely

Commissioner for Taking Affidavits
ADRIAN ZITA-BENNETT
LSO # 84848K

EZEL AYDONER

THIS IS **EXHIBIT "A"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Federal Court of Appeal | Cour d'appel fédérale

Date: 20220202

Docket: A-85-20

Citation: 2022 FCA 19

CORAM: **STRATAS J.A.**
RIVOALEN J.A.
MACTAVISH J.A.

BETWEEN:

SAFE FOOD MATTERS INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

and

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

Interveners

Heard by online video conference hosted by the registry on December 9, 2021.

Judgment delivered at Ottawa, Ontario, on February 2, 2022.

REASONS FOR JUDGMENT BY: RIVOALEN J.A.

CONCURRED IN BY: STRATAS J.A.
MACTAVISH J.A.

Federal Court of Appeal

Cour d'appel fédérale

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CORAM: **STRATAS J.A.**
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Interveners

REASONS FOR JUDGMENT

RIVOALEN J.A.

I. Introduction

[1] In 2002, Parliament overhauled the regulation of pest control products and passed the *Pest Control Products Act*, S.C. 2002, c. 28 (the Act) and its regulations. It created a comprehensive regulatory scheme for the registration and use of pesticides in Canada. The purpose of the Act is to protect human health and safety and the environment by regulating products used for the control of pests. It does this by preventing unacceptable risks to individuals and the environment from the use of pesticides. What emerges from the legislative and regulatory scheme are three pillars supporting the purpose of protecting public health and the environment: 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 to enhance decision-making and increase public confidence in it.

[2] The appellant, Safe Food Matters Inc., is a non-profit organization dedicated to promoting public health and protecting the environment by educating Canadians about the safety of food production technologies.

[3] The respondent, the Attorney General of Canada, represents the Pest Management Regulatory Agency (the PMRA), a branch of Health Canada responsible for the regulation of pesticides under the Act. The PMRA acts on behalf of the Minister of Health.

[4] An example of a pest control product regulated under the Act is glyphosate, the active ingredient in products such as Roundup. In 1976, glyphosate was registered for use in Canada and has been continuously registered for use since then. In 2005, the PMRA gave approval to a label expansion that allowed glyphosate to be used as a pre-harvest desiccant on a variety of crops, including chickpeas. In 2009, the PMRA gave notice of its intention to re-evaluate glyphosate to determine whether it should remain registered for use. On April 13, 2015, the PMRA made public a proposed re-evaluation decision. In response to the proposed re-evaluation decision, the appellant provided written comments and participated in the public consultation process.

[5] In 2017, after completing the public consultation process, the PMRA issued a re-evaluation decision permitting the continued registration of glyphosate products for use in Canada. In broad terms, the PMRA did not agree with the appellant's written comments.

[6] The release of the PMRA's re-evaluation decision triggered another right under the Act. Sixty days after a re-evaluation decision is released, subsection 35(1) of the Act allows any person to object to it with reasons. Here, the appellant did just that. In particular, following the process set out in the Act, the appellant filed a notice of objection (the NOO) to the re-evaluation decision. It presented nine objections that, in its view, raised "scientifically founded doubt" about the validity of the PMRA's evaluations concerning glyphosate products. It hoped the PMRA would exercise its statutory discretion to appoint a review panel in accordance with subsection 35(3) of the Act to consider the subject matter of the objections raised in the NOO, with a view to confirming, reversing or varying the re-evaluation decision.

[7] Section 4 of the *Review Panel Regulations*, S.O.R./2008-22 (the Regulations) provides that the review panel shall consist of one or more expert scientists who are independent of government and free from any actual or potential conflict of interest in relation to the decision under review.

[8] Subsection 35(5) of the Act requires the PMRA to provide written reasons without delay to the person who filed the notice of objection if a decision is made not to establish a review panel.

[9] On January 11, 2019, in written reasons, the PMRA dismissed the objections raised in the appellant's NOO and exercised its discretion not to establish a review panel (the PMRA Decision). The PMRA Decision is the decision the appellant challenges in this case.

[10] The PMRA found the issues raised in the appellant's NOO did not meet the criteria outlined in section 3 of the Regulations. Section 3 requires the Minister of Health to take the following factors into account in determining whether it is necessary to establish a review panel:

a) Whether the information in the NOO 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.

[11] The appellant, Safe Food Matters Inc., applied to the Federal Court for judicial review of the PMRA Decision. On February 13, 2020, the Federal Court dismissed the application (*McDonald v. Canada (Attorney General)*, 2020 FC 242 (*per* Simpson J.) (the Federal Court Decision)). Safe Food Matters Inc. now appeals to this Court.

[12] For the following reasons, I would allow the appeal, quash the PMRA Decision and remit the matter back to the PMRA for reconsideration in accordance with the guidance offered in these reasons.

[13] For ease of reference, section 35 of the Act and section 3 of the Regulations are appended to these reasons.

II. The Standard of Review

[14] As this appeal is from a judgment on a judicial review application, in accordance with the Supreme Court of Canada's decision in *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at paragraphs 45-46 [*Agraira*], this Court is required to step into the shoes of the Federal Court. We must determine whether the Federal Court selected the appropriate standard of review and, if it did, whether it applied it properly. Recently, the Supreme Court of Canada in *Northern Regional Health Authority v. Horrocks*, 2021 SCC 42, 462 D.L.R. (4th) 585, declined the invitation to reconsider *Agraira* and confirmed that its principles continue to apply.

[15] The parties agree that the question for us is whether the PMRA Decision is reasonable, having regard to the reasonableness standard of review established by the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v. Vavilov,* 2019 SCC 65, 441 D.L.R. (4th) 1 [*Vavilov*].

III. The PMRA Decision under Review

[16] In its NOO, the appellant raised nine objections. The main basis for the first four objections is that when glyphosate is applied, for pre-harvest desiccation purposes in certain crops such as chickpeas, the residue levels of glyphosate may exceed the permitted maximum levels and may therefore be of concern to human health. These objections included concern that the maximum residue level of glyphosate may be exceeded because of a purported increase in dietary consumption of certain crops such as chickpeas since 2010. These four objections were key to raising "scientifically founded doubt". The remaining five objections presented other arguments largely concerning enforcement issues and product labelling.

[17] The NOO provided several references in support of its objections from scientific studies, literature and government publications, as well as Health Canada policy documents. The NOO added that the re-evaluation decision did not consider certain evidence it provided.

[18] In the concluding paragraphs of the NOO, the appellant argued that Canadians are likely consuming crops that contain unacceptable levels of glyphosate residue and as a result, a review panel should be established to assess glyphosate in the context of its objections.

[19] In response to the NOO, the PMRA wrote a two-page letter consisting of seven paragraphs. The first two paragraphs of the letter confirmed the general purpose of a notice of objection and that the appellant's NOO has been reviewed and assessed in accordance with the Act and Regulations. The PMRA, paraphrasing section 2 of the Regulations, recounted that the purpose of a notice of objection is "to identify the area of science supporting the re-evaluation decision to which objection is taken, to provide the scientific basis of the objection and to request that the area of science in question be referred to a review panel for reconsideration and recommendation."

[20] The third paragraph stated that "[t]he PMRA has taken all reasonable measures to ensure impartiality in determining if a panel should be established." It added that "[t]he notice of objection, including the scientific rationale, was assessed by a team of PMRA evaluators who were not involved in the original re-evaluation decision" and explained that "[t]his team provided recommendations as to the requirement for a review panel based on the validity and the scientific plausibility of the issues raised in the notice." In addition, the third paragraph cited the factors the PMRA must take into account pursuant to section 3 of the Regulations. It offered no definition of the term "scientifically founded doubt".

[21] The fourth paragraph listed the information received from the appellant that the PMRA reviewed.

[22] The fifth paragraph set out the PMRA's decision in response to the NOO: "The information which you submitted in support of your objection does not meet either of those

factors and, accordingly, does not provide a basis for the establishing of a review panel" and so "[a]s a consequence, a review panel will not be established to reconsider the regulatory decision in response to your request."

[23] The sixth paragraph introduced the attachment to the letter. The attachment contained six pages of scientific explanation from the PMRA to certain objections raised in the appellant's NOO.

[24] The seventh and last paragraph of the letter provided contact information and reference numbers to the PMRA decision in case the appellant had any questions.

IV. The Federal Court Decision

[25] The Federal Court correctly identified reasonableness as the standard of review to be applied to the PMRA Decision.

[26] The Federal Court noted that the meaning of the term "scientifically founded doubt" found in subsection 3(a) of the Regulations had not been defined in previous jurisprudence and so it proceeded with its own statutory interpretation of this term. The Federal Court determined that "scientifically founded doubt" about the validity of the evaluations "must be demonstrated by at least one controlled peer reviewed study published in a reputable journal that contradicts or raises a reasonable doubt about the Evaluations' conclusions" (Federal Court Decision at paras. 17-20).

[27] The Federal Court conducted its own detailed analysis of whether the objections put forward in the appellant's NOO raised scientifically founded doubt about the validity of the PMRA's risk evaluations and found that they did not.

[28] The Federal Court stated that "[s]tatutory interpretation is not the purview of a panel of expert scientists" and concluded that Safe Food Matters Inc. had "not shown in their NOO that there exists scientifically founded doubt about the validity of the Evaluations" (Federal Court Decision at paras. 73 and 74).

[29] As a result, the Federal Court determined that the PMRA Decision not to establish a review panel was reasonable.

V. Positions of the Parties

A. *The Appellant's Position*

[30] The appellant submits that the PMRA Decision was unreasonable for four reasons:

1. It failed to interpret the statutory scheme governing the criteria for assessing the NOO;

2. It did not comply with the statutory scheme, as properly interpreted;

3. It failed to address the impact on individuals; and

4. It failed to address the appellant's evidence and submissions.

[31] In the appellant's view, the PMRA Decision also fails to meet the requisite standard of justification, transparency and intelligibility by providing insufficient reasoning (*Vavilov* at para. 99).

[32] During oral submissions, the appellant focused its argument on the lack of reasoned explanation on the part of the PMRA and its failure to justify its reasoning in relation to the relevant factual and legal constraints that bear on the PMRA Decision.

B. *The Respondent's Position*

[33] The respondent submits that the PMRA Decision is consistent with the statutory scheme and that the PMRA reasonably addressed the appellant's objections, namely those concerning how moisture and maturity affect pesticide levels in crops and the PMRA's dietary consumption data. Read in context, the PMRA's reasons were sufficient and its decision not to establish a review panel was reasonable.

C. *The Interveners' Position*

[34] David Suzuki Foundation, Environmental Defence Canada Inc. and Friends of the Earth Canada/Les Amis de la Terre, the interveners in this appeal, focus on the Federal Court's definition of "scientifically founded doubt". Among other things, they argue that Parliament did not intend that the PMRA be limited to considering only those objections that are supported by a peer-reviewed study. After all, objections may be made by any member of the public, not just scientists who know about and can access peer-reviewed studies.

[35] Consistent with the objectives of the notice of objection process—namely to provide concerned parties an opportunity to highlight areas of reconsideration for the PMRA—the interveners submit that "scientifically founded doubt" must be read harmoniously with the overall process of risk prevention found in the Act.

[36] The interveners argue that, read in context, "scientifically founded doubt" simply amounts to a credible doubt, based on available information, whether the PMRA has met the high acceptable risk threshold. Moreover, it would be unfair to place the same standard on members of the public in an objection process as that imposed on the registrant in a registration process to establish acceptable risk.

VI. Analysis of the PMRA Decision

[37] At the outset, it is important for us to be reminded that under the Act, it is for the members of the PMRA, not the Federal Court or this Court to decide on the merits of whether the PMRA should exercise its discretion under section 35 of the Act to appoint a review panel. It is clear that the PMRA is the merit-decider, not this Court. (See *Association of Universities and Colleges of Canada v. Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22, 428 N.R. 297 at paras. 17 and 18 [*Universities and Colleges of Canada*]; *Delios v. Canada (Attorney General)*, 2015 FCA 117, 472 N.R. 171 at para. 41; *Sexsmith v. Canada (Attorney General)*, 2021 FCA 111 at para. 32 [*Sexsmith*]; *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157, 185 C.P.R. (4th) 83 at para. 24 [*Alexion*]).

[38] Likewise, according to the principles enunciated in *Vavilov*, it is for the members of the PMRA to interpret their home statute, not the Federal Court or this Court (*Vavilov* at paras. 108-110 and 119).

[39] Therefore, on judicial review or in an appeal from a judicial review, acting under the reasonableness standard, we do not re-weigh the evidence before the PMRA, we do not second-guess the exercise of its discretion, and we do not proceed with our own statutory interpretation of the Act and its Regulations. Under this legislative regime, that is the job of the PMRA. As long as its interpretation of the Act and Regulations is reasonable, and the reasons it provides for its decision are justifiable, clear and intelligible, we owe deference and should not interfere

(*Vavilov* at paras. 75, 83, 85 and 86; *Canada (Minister of Citizenship and Immigration) v. Mason*, 2021 FCA 156 at paras. 41 and 42 [*Mason*]).

[40] While the administrative decision-maker is responsible for interpreting its statute, there is no need for it to mimic how courts go about it (*Vavilov* at paras. 119 and 120). Whatever interpretative approach the decision-maker takes, however, its task is to ensure that the interpretation of the statutory provision is consistent with the text, context and purpose of the provision (*Vavilov* at para. 120; *Canada Post Corp. v. Canadian Union of Postal Workers*, 2019 SCC 67, 441 D.L.R. (4th) 269 at para. 42 [*Canada Post*]). In other words, the decision-maker must grapple with the issue of the proper meaning of the legislation before it and explain why its decision is within legislative constraints (*Mason* at paras. 34 and 35; *Alexion* at para. 20).

[41] At the very least, a reviewing court must be "able to discern the interpretation adopted by the decision maker from the record and determine whether that interpretation is reasonable" (*Vavilov* at para. 123; *Canada (Attorney General) v. Kattenburg*, 2021 FCA 86, 458 D.L.R. (4th) 744 at para. 16 [*Kattenburg*]; *Yu v. Richmond (City)*, 2021 BCCA 226, 54 B.C.L.R. (6th) 71 at para. 53).

[42] In the end result, a decision-maker is constrained by the specifically worded statutory scheme under which it draws its authority. If the decision-maker fails to respect specifically worded statutory provisions, reversal of the decision can result (*Entertainment Software Association v. Society of Composers, Authors and Music Publishers of Canada*, 2020 FCA 100, [2020] F.C.J. No 671 (QL) at paras. 33 and 35).

[43] With these principles in mind, for the following reasons, I am of the view that the PMRA Decision is unreasonable.

A. *The PMRA Decision fails to interpret the governing legislation*

[44] To start, I note that the PMRA Decision does not refer to past decisions dealing with the manner in which it exercises its discretion under subsection 35(3) of the Act. The parties did not place any such decisions before this Court and there is no jurisprudence to assist the PMRA.

[45] This is the first time that this Court is called upon to review a decision of the PMRA.

[46] As mentioned in paragraph 39 above, it is for the PMRA to interpret its own legislation in a way that is reasonable and in a manner that can be understood. Expert scientists employed by government may well be tasked with reviewing the science raised in the NOO, but the PMRA is tasked with the interpretation of the Act and Regulations in the context of the scientifically-based objections in the NOO and the record. The PMRA's responsibility is to consider the scientific basis for the objection and the corresponding scientific advice it receives from expert scientists employed by government. With this information in hand, and in coming to its decision of whether it should exercise its discretion to establish a review panel, the PMRA must look to the relevant provisions of the Act that will inform its decision. As well, it must take into account the two factors set out in subsection 3(a) and 3(b) of the Regulations which are: (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. While the PMRA does have discretion, it can only exercise such discretion once both of these factors are considered.

[47] Therefore, even where a decision-maker like the PMRA has the discretion to make a particular decision, such as whether it is necessary to establish a review panel, its discretion is not untrammeled. The exercise of discretion must comply with the rationale and purview of the Act (*Vavilov* at para. 108).

[48] The Act's primary purpose is the protection of individuals and the environment, and it achieves this protection by: i) requiring a scientifically-based approach to the evaluation of risks posed by the use of pest control products; ii) requiring periodic re-evaluations of registered pest control products, such as is the case here; and iii) inviting public participation in the regulatory scheme.

[49] In addition to the Act, the PMRA's discretion is further constrained by making it subject to the two factors set out in section 3 of the Regulations. That is, section 3 of the Regulations limits the PMRA's discretion by dictating factors that it must consider in arriving at its decision as to whether it is necessary to establish a review panel. While it can consider other factors, it must consider at least those two factors.

[50] The PMRA Decision falls short of these fundamental requirements. I will provide a few specific examples to clarify my point.

[51] The PMRA does not justify its decision by looking to the preamble of the Act, which outlines the need to prevent unacceptable risks to the public from the use of pest control products. The PMRA Decision fails to consider the definitions of “health risk” and “acceptable risks” set out in subsections 2(1) and 2(2) of the Act. It also is silent on the primary objective of the legislation, being the prevention of unacceptable risks to individuals and the environment from the use of pest control products, as set out in subsection 4(1) of the Act.

[52] The PMRA Decision does not explain the scientific approach it must take in evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable as outlined in subsection 19(2) of the Act.

[53] While it identified the appropriate section of the Regulations applicable to a review of a notice of objection, the PMRA Decision provided no explanation whatsoever as to the meaning of the term “scientifically founded doubt” found in subsection 3(a) of the Regulations. Further, nowhere in its reasons did it tackle the question of whether the advice of expert scientists would assist in addressing the subject matter of the objection, as it was required to do under subsection 3(b) of the Regulations. Both of these factors must be addressed.

[54] Rather, in its decision not to establish a review panel, the PMRA simply provided a conclusory statement that the NOO did not meet either factor set out in section 3 of the Regulations. We simply cannot discern from the PMRA Decision why the PMRA concluded that the objections raised in the NOO did not meet either of those factors. This is particularly important given the statutory requirement for the PMRA to provide written reasons under

subsection 35(5) of the Act, which is designed to make the public participation meaningful. The failure to provide any explanation of either of these factors is critical and this is sufficient, in my view, to render the PMRA Decision unreasonable.

[55] Here, the PMRA has not demonstrated through its reasons that it was alive to the need to interpret the Act and the Regulations and, in particular, to identify the essential elements of the text, context and purpose of the Act and the Regulations as it was required to do (*Mason* at para. 42; *Sexsmith* at para. 35; *English v. Richmond (City)*, 2021 BCCA 442 at paras. 68-75).

[56] The PMRA has not fulfilled its task of ensuring that the interpretation of subsection 35(3) of the Act and section 3 of the Regulations is consistent with the text, context and purpose of the provisions (*Vavilov* at para. 120; *Canada Post* at para. 42). It did not grapple with the issue of the proper meaning of the legislation before it and explain why its decision is within legislative constraints (*Mason* at paras. 34 and 35; *Alexion* at para. 20).

[57] This failure to provide a legislative interpretation renders the PMRA Decision unreasonable (*Alexion* at paras. 30-32).

B. *The record does not assist in discerning the PMRA Decision*

[58] I have already concluded that the PMRA Decision is unreasonable because it lacks any legislative interpretation of the relevant provisions of the Act and most importantly, does not provide any interpretation of the mandatory factors it must consider under section 3 of the

Regulations. Nevertheless, I will continue my analysis by looking at the record to determine whether it can assist me in discerning the basis for the PMRA Decision (*Vavilov* at para. 123; *Kattenburg* at para. 16). I conclude that it does not. From the reasons offered in light of the record, we simply do not know *why* a review panel might not assist in this case in considering whether the re-evaluation decision should be confirmed, reversed or varied in some way.

[59] Here, the record contains no more than a smattering of references to "concerns", "scientifically founded doubt[s]" and "scientific grounds". Even if we could discern an interpretation from these few references, the PMRA Decision remains unreasonable. Under the most generous interpretation, these references relate to the quality of the objections before the PMRA. That is, they speak to the requirement for a "scientifically founded doubt" under subsection 3(a) of the Regulations. (See Science Management Committee Briefing dated June 29, 2017, Appeal Book, tab 6, exhibit P, p. 815; Science Management Committee Briefing dated November 15, 2018, Appeal Book, tab 6, exhibit P, p. 843; PMRA's Memorandum to Charles Smith dated July 16, 2018, Appeal Book, tab 6, exhibit P, pp. 855 ff.; Glyphosate Notice of Objection, Appeal Book, tab 33, pp. 2593 ff.; PMRA's Memorandum to Catherine Adcock dated August 30, 2018, tab 34, pp. 2617 ff.).

[60] However, subsection 3(a) of the Regulations is only one of two factors the PMRA was tasked to interpret, as set out in paragraphs 53 and 54 of these reasons. Subsection 3(b) says that the PMRA shall assess "whether the advice of expert scientists would assist in addressing the subject matter of the objection." In other words, the PMRA was required to evaluate factors beyond the four corners of the NOO. The record does not show a shred of analysis beyond the

scientific aspects of the decision itself. Therefore, we can discern no interpretation of subsection 3(b) of the Regulations from the record.

[61] The PMRA did not explicitly or implicitly consider the text, purpose or context of section 35 of the Act or section 3 of the Regulations. If it did so, its reasons, explicit or implicit, cannot be discerned from the record. The PMRA Decision is unreasonable as it fails to meet the requisite standard of justification, transparency and intelligibility (*Vavilov* at para. 99; *Alexion* at para. 66).

[62] I have concluded that the PMRA Decision is unreasonable because it lacks any interpretation of the Act and Regulations, and I am unable to discern a legislative interpretation from the record. Thus, I need not consider the appellant's other arguments because these conclusions are sufficient to end my review.

C. *The Federal Court's definition of "Scientifically Founded Doubt"*

[63] I wish to add a word or two on the Federal Court's interpretation of the term "scientifically founded doubt". I agree with the parties, including the interveners, that the Federal Court erred when it provided its own interpretation of this term. How this term is to be interpreted is the job of the PMRA, not the Federal Court. The Federal Court is the reviewing court, not the merits-decider (*Universities and Colleges of Canada*).

D. *Guidance*

[64] As this case represents the first time that this Court is reviewing a decision of the PMRA, it may be useful to provide some guidance to the PMRA when it goes about its redetermination. This is particularly important, given the number of years that have passed since the re-evaluation decision was made public. Further, it would be unfortunate for the redetermination decision to come back to the Federal Court, and possibly this Court, for a review on substantive unreasonableness. This guidance may avoid a possible "endless merry-go-round of judicial reviews and subsequent reconsiderations" (*Vavilov* at para. 142; *Sexsmith* at para. 31).

[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.

[67] In offering this guidance, consistent with my role as an appellate judge on a judicial review, I am not proposing any particular outcome on the merits of the matters before the PMRA.

VII. Conclusion

[68] For these reasons, I would allow the appeal. Making the judgment the Federal Court should have made, I would grant Safe Food Matters Inc.'s application for judicial review, quash the PMRA Decision and remit the matter back to the PMRA for redetermination in light of the guidance provided in these reasons. As the appellant is not seeking costs, I would award none.

"Marianne Rivoalen"
J.A.

"I agree.
David Stratas J.A."

"I agree.
Anne L. Mactavish J.A."

ANNEX

***Pest Control Products Act*, S.C. 2002, c. 28**	***Loi sur les produits antiparasitaires*, L.C. 2002, ch. 28**
Reconsideration of Decisions	**Examen des décisions**
Notice of objection to registration decisions	**Avis d'opposition - homologation**
35 (1) Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public	35 (1) Dans les soixante jours suivant celui où l'énoncé de décision visé au paragraphe 28(5) est rendu public, toute personne peut déposer auprès du ministre, selon les modalités que celui-ci fixe, un avis d'opposition à la décision visée aux alinéas 28(1)a) ou b).
Notice of objection to authorization decisions	**Avis d'opposition – autorisation d'exportation**
35 (2) Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision to authorize the export of a pest control product or to amend or cancel an authorization within 60 days after a notice referred to in subsection 33(6) or 34(4) is made public.	35 (2) Dans les soixante jours suivant celui où l'avis visé aux paragraphes 33(6) ou 34(4) est rendu public, toute personne peut déposer auprès du ministre, selon les modalités qu'il fixe, un avis d'opposition à la décision d'autoriser l'exportation d'un produit antiparasitaire ou de modifier ou de révoquer l'autorisation d'exportation.
Establishment of a review panel	**Constitution d'une commission d'examen**
35 (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.	35 (3) Le ministre peut, après réception de l'avis d'opposition, constituer, en conformité avec les éventuels règlements, une commission d'examen, composée d'un ou de plusieurs individus, chargée d'examiner la décision prise et de recommander soit sa confirmation, soit son annulation, soit encore sa modification.

Notice of review panel

35 (4) The Minister shall give public notice of the establishment of a review panel.

Avis – commission d'examen

35 (4) Le ministre publie un avis de la constitution de la commission d'examen.

Reasons to be provided if panel not established

35 (5) If the Minister does not establish a panel, the Minister shall provide written reasons without delay to the person who filed the notice of objection.

Non-constitution motivée

35 (5) Si le ministre décide de ne pas constituer de commission d'examen, il communique sans délai ses motifs écrits à la personne qui a déposé l'avis.

Terms of reference and procedure

35 (6) The Minister may determine the terms of reference of a review panel and the procedure for the review, and may at any time change them.

Mandat et procédure

35 (6) Le ministre peut fixer le mandat de la commission et prévoir la procédure d'examen et, à tout moment, les modifier.

Representations

35 (7) A review panel shall give any person a reasonable opportunity to make representations in respect of the decision under review, in accordance with the terms of reference.

Observations

35 (7) La commission est tenue, en conformité avec son mandat, de donner à toute personne la possibilité de présenter ses observations sur la décision faisant l'objet de l'examen.

Public access

35 (8) Subject to subsections 44(3) and (6), the hearings of a review panel shall be open to the public.

Accessibilité

35 (8) Sous réserve des paragraphes 44(3) et (6), les audiences de la commission sont publiques.

Information to be placed in Register

35 (9) A review panel shall give the information submitted to it to the Minister, who shall place it in the Register.

Inscription au Registre

35 (9) Les renseignements fournis à la commission sont remis au ministre, qui les verse au Registre.

***Review Panel Regulations*, S.O.R./2008-22**	***Règlement sur les commissions d'examen*, D.O.R.S./2008-22**
Establishing Review Panels	**Constitution des commissions d'examen**
3 The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:	3 Le ministre prend en compte les facteurs ci-après pour déterminer s'il y a lieu de constituer une commission d'examen :
(*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	*a*) l'avis d'opposition soulève un doute, sur la base de renseignements fondés scientifiquement, quant à la validité des évaluations qui ont été faites de la valeur du produit antiparasitaire et des risques sanitaires et environnementaux qu'il présente et qui ont mené à la décision contestée;
(*b*) whether the advice of expert scientists would assist in addressing the subject matter of the objection.	*b*) l'obtention de l'avis de scientifiques serait susceptible de favoriser le règlement de l'objet de l'opposition.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-85-20

APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE SIMPSON OF THE FEDERAL COURT DATED FEBRUARY 13, 2020, NO. T-277-19

STYLE OF CAUSE:	SAFE FOOD MATTERS INC. v. ATTORNEY GENERAL OF CANADA, and DAVID SUZUKI FOUNDATION, ENVIRONMENTAL DEFENCE CANADA INC. and FRIENDS OF THE EARTH CANADA/LES AMIS DE LA TERRE
PLACE OF HEARING:	BY ONLINE VIDEO CONFERENCE
DATE OF HEARING:	DECEMBER 9, 2021
REASONS FOR JUDGMENT BY:	RIVOALEN J.A.
CONCURRED IN BY:	STRATAS J.A. MACTAVISH J.A.
DATED:	FEBRUARY 2, 2022

APPEARANCES:

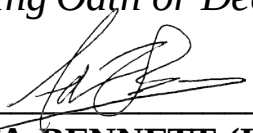
Andrea Gonsalves Karen Bernofsky	FOR THE APPELLANT
Andrea Bourke Karen Lovell Elizabeth Koudys	FOR THE RESPONDENT
Laura Bowman Ian Miron	FOR THE INTERVENERS

SOLICITORS OF RECORD:

Stockwoods LLP Toronto, Ontario	FOR THE APPELLANT
A. François Daigle Deputy Attorney General of Canada	FOR THE RESPONDENT
Ecojustice Toronto, Ontario	FOR THE INTERVENERS

THIS IS **EXHIBIT "B"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Health Canada / Santé Canada

Pest Management Regulatory Agency / Agence de réglementation de la lutte antiparasitaire

Reference No. 2017-3047

September 29, 2022

Mary Lou McDonald
Safe Food Matters Inc.
9 Boardwalk Dr. Unit 107
Toronto, ON
M4L 6T1

Dear Ms. McDonald,

Re: Notice of Objection to Re-evaluation Decision RVD2017-01, Glyphosate

Pursuant to the Federal Court of Appeal's (FCA) judgment in *Safe Food Matters Inc. v. Canada (Attorney General)*, 2022 FCA 19, quashing the decision of Health Canada's Pest Management Regulatory Agency (PMRA) dated January 11, 2019, and remitting the matter back to the PMRA for redetermination in accordance with the FCA's reasons, your notice of objection, filed under subsection 35(1) of the *Pest Control Products Act* (*PCPA*), regarding the re-evaluation decision for glyphosate has now been redetermined in accordance with the *PCPA*, the *Review Panel Regulations* and the FCA's reasons.

The Minister of Health's primary objective under the *PCPA* subsection 4(1) is to prevent unacceptable risks to individuals and the environment from the use of pest control products. As noted in the preamble of the *PCPA*, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health and the environment, both before and after registration, and applies to the regulation of pest control products throughout Canada; and that pest control products of acceptable risk be registered for use only if it is shown that their use would be efficacious and if conditions of registration can be established to prevent adverse health and environmental impacts.

Legislative and Regulatory Framework for Decision

The risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health or 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: subsection 2(2) of the *PCPA*. The objections submitted challenged PMRA's assessment of the health risks in relation to the re-evaluation decision for glyphosate.

Health risk is defined in the *PCPA* subsection 2(1) as follows:

> ***health risk***, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

All registered pesticides must be re-evaluated by Health Canada's PMRA, on behalf of the Minister of Health, to ensure that they meet current health standards. When evaluating the health risks of a pesticide and determining whether those risks are acceptable, subsection 19(2) of the *PCPA* requires PMRA to apply a scientifically based approach. The science-based approach to assessing pesticides considers both the toxicity of and the level of exposure to a pesticide in order to fully characterize and assess risk. The PMRA uses a comprehensive body of robust scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pesticides. The integration of scientific information is an iterative process that is repeated for individual studies as well as across similar studies for a particular line of evidence. Multiple lines of evidence related to hazard and exposure are then integrated into an overall risk assessment conclusion. This approach allows for the protection of human health through the application of appropriate and effective risk management strategies, consistent with the purpose described in the preambular text and the primary objective of the *PCPA*, set out above.

The PMRA's approach to risk assessment is outlined in: risk-management-pest-control-products-eng.pdf

Before making a final decision, a re-evaluation is subject to public consultation in accordance with section 28 of the *PCPA.* All stakeholders and the public are encouraged to be engaged in the consultation process and submit information to inform PMRA's development of the final regulatory decision. PMRA considers all comments and information received during the consultation period, which are addressed in the final decision.

Section 35 of the *PCPA* provides any member of the public an opportunity to file a Notice of Objection (NoO) within 60 days after the final re-evaluation decision is published. The NoO process permits PMRA to seek the assistance of an external expert review panel in response to the NoO, where warranted, and provides another opportunity for an interested member of the public to participate in the scientific aspects of the re-evaluation process. 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.

The *Review Panel Regulations* ("*Regulations*") support the NoO process under the *PCPA.* Subsection 2(c) of the Regulations requires a scientific basis for the objection to the evaluations on which the decision was based. Subsection 2(d) of the *Regulations* requires that the Notice of Objection also include the evidence to support the objection, including scientific reports or test data. Since NoOs are filed after a lengthy scientific 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.

Should the criteria in subsection 35(1) of the *PCPA* and section 2 of the *Regulations* be met, the PMRA reviews a Notice of Objection to determine whether to establish a review panel pursuant to subsection 35(3) of *the PCPA.*

Section 3 of the *Regulations* states:

The Minister shall take the following factors into account in determining whether it is necessary to establish a review panel:

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

The PMRA developed the Notice of Objection Review Panel Criteria for the two factors in section 3 of the *Regulations* that PMRA is directed to take into account in its consideration of whether an external review panel should be established.

In evaluating a Notice of Objection, the PMRA will generally consider the following Notice of Objection Review Panel Criteria**:**

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[a] information available and considered by PMRA at the time of 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

[a] **Reliable Science**: science that is credible and unbiased. Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments.

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 a 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?

Summary of the Notice of Objection under Review

The following information was received and reviewed in support of your Notice of Objection:

- Notice of Objection Form
- Notice of Objection document, including detailed arguments and additional references.
- CFIA test results for Glyphosate in Chickpea and in Wheat Bran.

The Notice of Objection set out nine points summarizing the arguments presented to support the objection:

1) Desiccation with Glyphosate on Crops Causes MRL Exceedance
2) Evidence of Dietary Exposure to Glyphosate as a Desiccant Not Examined in PRVD2015-01
3) Evidence that Dietary Exposure of Desiccated Crops has Increased
4) MRLs for Unregistered Products Have Not Been Set as Required by the *Act*
5) Label Amendments Don't Address the Risk
6) No Consideration of Whether Labels are Followed
7) Enforcement of Any Imposed Label Requirements on Desiccants Not Likely
8) Unlikely that Following Labels Will Bring No Harm, since Statutory Regime Contemplates Exceedances of MRLs Even When Labels are Followed
9) Reductions of Safety Factor Without Scientific Rationale

PMRA's Consideration of the Objections:

The following details PMRA's response to each of the objections and takes into account the Notice of Objection Review Panel Criteria, set out above, to guide the determination as to whether an external review panel should be established for one or more of the objections, based on the factors set out in section 3 of the *Regulations.*

Objection 1: "Desiccation with Glyphosate on Crops Causes MRL Exceedances"

Safe Food Matters (SFM) Inc. cited peer-reviewed scientific literature indicating that the early application of glyphosate as a desiccant (i.e., applying glyphosate to a crop earlier than the registered label use), or the application of glyphosate when seed/grain moisture content is too high, resulted in exceedances of Maximum Residue Limits (MRLs) for some crops. SFM also referenced a third-party

analysis of data obtained from the Canadian Food Inspection Agency (CFIA) that reported exceedances in wheat bran and chickpea samples. It was their assertion that MRL exceedances endanger human health.

Criterion 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?

Yes, this objection is directly linked to the evaluation of the pest control product. However, the objection states that glyphosate is being used as a desiccant in pre-harvest applications in Canada. Glyphosate is registered as a pre-harvest use and not as a desiccant as explained in detail below, and the PMRA assessed the pre-harvest use of glyphosate.

Pre-harvest use versus Desiccant use:

The basis of this objection is not reasonably expected to affect the outcome of the health assessment because glyphosate is approved for "pre-harvest use", not as a "desiccant".

Crops naturally mature and begin to senesce in the fall. This is the natural drying down of the crop. When weeds are present in the mature crop, the drying-down process is slower and can delay harvest operations. In addition, the presence of the weeds makes it more difficult to harvest the crop. Killing the weeds with an herbicide allows the crop to dry down more rapidly, but, in the case of glyphosate, this is through the removal of the green weed plants, not by direct drying of the crop by the herbicide.

Herbicides that are registered for use as a crop desiccant are typically **fast-acting contact herbicides** that quickly kill off the living crop, and the labels of such products clearly indicate the crop desiccant use. In contrast to a desiccant use of an herbicide, some herbicides are registered for pre-harvest weed control. When this is the case, the label will clearly indicate the pre-harvest application timing, similar to a crop desiccant use, but the label indicates that the pre-harvest application is for the purpose of weed control, typically control of perennial or winter annual weeds. When herbicides are applied to a crop at pre-harvest for weed control, the removal of the green, living weeds can facilitate harvesting operations, as the dead weeds pass more easily through the combine, but also because removal of the weeds allows for the natural drying down of the crop as it senesces. It is the removal of the weeds that contributes indirectly to the **natural drying** of the crop, not the effect of the herbicide on the crop itself.

Glyphosate-based herbicides are not registered for use as a crop desiccant. There are no explicit crop desiccant uses on glyphosate-based herbicide labels. The characteristics of glyphosate are **not amenable** to its use as a desiccant – it is slower acting, particularly under cooler environmental conditions leading up to harvest, and it is required to be translocated within the plant to be effective. Glyphosate is registered for pre-harvest application to certain crops (among other registered application timings), and the labels are clear that the pre-harvest applications are for the primary purpose of controlling perennial weeds that are present at the time of harvest. The label then indicates there may be additional harvest management benefits, by drying down crop and weed vegetative growth. **This reference to drying down**

of the crop is in relation to the natural drying process that is further facilitated by the removal of weeds present at harvest; it is not a crop desiccant use. While the wording in the final glyphosate re-evaluation decision document (RVD2017-01) does not precisely distinguish a crop desiccant use from a pre-harvest weed control use, it is the product labels and the claims on them that specify and govern the registered uses of a product.

The Notice of Objection claimed that glyphosate is used on crops in Canada as a pre-harvest desiccant. As stated above, it is important to note that glyphosate is registered in Canada and elsewhere for **pre-harvest** use on several crops for weed control, for the purpose of killing green weed biomass present in the field at the time of harvest, thereby facilitating harvest. Although the terms "desiccant" and "pre-harvest use" are sometimes used interchangeably, particularly by media and public communications, to refer to the harvest benefit of glyphosate, there is a technical difference. As noted above, glyphosate is a registered pre-harvest use intended to kill green weed biomass present in the field thereby helping the natural drying down of the crop, but it is not registered as a "food crop desiccant" in Canada. This is fully explained in Lovell 2012[b], one of the articles referenced in the Notice of Objection:

> Although glyphosate products are not desiccants, it's a common misconception that glyphosate applied prior to harvest will act as a crop desiccant. "There is often a blurring of the term," says [Clark] Brenzil [provincial weed specialist with the Saskatchewan Ministry of Agriculture]. "Farmers will often say 'we're desiccating with glyphosate' and that's not the case. Glyphosate kills plants; then it's left to Mother Nature to dry them down."
>
> More correctly, says Brenzil, farmers use a pre-harvest application of glyphosate to control perennial weeds. "The glyphosate circulates in the plant and gets down to the roots and controls that perennial weed," he says. "Pre-harvest is a particularly good time of year to achieve that, particularly the further north you go."

Glyphosate is approved for pre-harvest use only when the moisture content of the seed/grain of the target crop is less than 30%. This specific use of glyphosate, that is, the "pre-harvest use", is the term used herein in response to this Notice of Objection.

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?

The Notice of Objection cited an opinion piece by Mitra (2017) that analyzed CFIA monitoring data from food samples tested for glyphosate residues in 2015-2016. However, Mitra inaccurately reported glyphosate MRL exceedances in chickpea and wheat bran commodities. None of the samples in the Mitra report actually had residues that exceeded the MRL for chickpea (4 ppm for bean) or wheat bran (15 ppm for wheat milling fractions, excluding flour). As such, this analysis by Mitra incorrectly labelled any level of glyphosate in these commodities as a violation, yet there were no MRL exceedances. Therefore, this analysis by Mitra is not reliable science and does not meet the criteria for scientific acceptability.

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[b] Lovell, A. 2012. "Don't Use Desiccants to Hasten Maturity." *Grainews*, Last assessed online May 26, 2022 at https://www.grainews.ca/features/dont-use-desiccants-to-hasten-maturity

Further to this, the summary report published by the CFIA entitled "Safeguarding with Science: Glyphosate Testing in 2015-2016'' (which was not cited in the NoO) indicated that only 1.3% of all samples tested had residues that exceeded MRLs (with 3 MRL violations for chickpea **flour,** which also were not identified in 2017 Mitra report). These non-compliant data for chickpea flour were evaluated by the PMRA, and no human health concerns were identified. Hence, the information provided in relation to an opinion piece on CFIA data in the NoO (Mitra, 2017) does not meet the criteria for scientific acceptability.

Data regarding glyphosate application when seed/grain moisture content is higher than 30%, resulting in a possible MRL exceedance, was previously taken into consideration during the re-evaluation of glyphosate. While sources of some of the data cited in the Notice of Objection are different than the sources considered in the re-evaluation, the data reviewed by PMRA in setting the pre-harvest use conditions and also taken into account at the time of the re-evaluation was similar in nature to the data presented in the Notice of Objection, resulting in the same conclusions.

The studies cited in the Notice of Objection, which investigated the relationship between seed/grain moisture content and residue levels, show that residues of glyphosate can exceed the maximum residue limits (MRLs) for specific crops if applied as a pre-harvest treatment when the seed moisture content in wheat, canola, red lentils, dry beans and field peas is 40% or greater. This information is scientifically valid and similar data were taken into consideration during the registration and re-evaluation of glyphosate, which resulted in the specification on registered glyphosate products labels in Canada, that application **must** be conducted at **less than 30%** moisture content. MRLs for these specific crops were based on crop residue data that were conducted in accordance with this specific use pattern. In other words, as indicated in the response to comments provided in the final glyphosate re-evaluation decision document (RVD2017-01), glyphosate residues on specific food commodities were measured in crop field trial studies that were conducted according to how the product was intended to be used in accordance with conditions of registration, including the specified 30% or less seed moisture content. Crop field trial studies are required to register a pesticide for each specific use, as per PMRA Residue Chemistry Guidelines (Dir98-02). Therefore, the field trial data used for the establishment of MRLs for glyphosate also sets the conditions that must be adhered to in order to comply with the MRLs, that is, the maximum legally allowed amount of glyphosate residue that may remain on foods when glyphosate is used according to label directions. As such the information provided does not highlight any new scientific evidence not already considered in the evaluation and also previously addressed by the conditions of registration.

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

Assumptions made in the objection are incorrect. First, as noted earlier, the objection states that glyphosate is being used as a desiccant in pre-harvest applications in Canada. Glyphosate is registered as a pre-harvest use and not as a desiccant, and the PMRA assessed the pre-harvest use of glyphosate.

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[c] **Reliable Science**: science that is credible and unbiased. .Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments.

Second, while Safe Food Matters Inc. correctly stated that food containing a pesticide residue that does not exceed the established MRL does not pose a health risk concern, they made the incorrect assertion that foods that do exceed the established MRL necessarily pose a health risk and thus endanger human health.

MRL exceedances do not equate to a health risk:

This objection is not expected to affect the outcome of the health evaluation as the assumption that MRL exceedances pose a risk to human health is incorrect. In addition, the evidence provided in support of the objection, when considered with all scientifically reliable information available and considered by PMRA at the time of decision, does not present uncertainty in an aspect of the evaluation. MRL exceedance does not automatically equate to a human health risk.

MRLs are specified under the *PCPA* and are enforced by the Canadian Food Inspection Agency (CFIA) under the *Food and Drugs Act*. The conditions of registration, i.e., the label directions for use, are legal requirements that the user must follow in all circumstances. MRLs are set at a level that is reflective of Good Agricultural Practices[d], well below the amount of residue that could present a human health concern. MRLs are derived using a statistical method intended to ensure that maximum levels calculated for potential residues in treated foods of plant and animal origin will not be underestimated. MRLs are used for monitoring purposes to help ensure the safety of Canada's food supply. When Good Agricultural Practices are followed, including the use of pesticides according to the approved label directions/conditions, residues in foods should comply with MRLs. However, an exceedance of an MRL (see examples below), does not automatically equate to a health risk of concern. That said, when a pesticide residue level exceeds the MRL, follow-up actions for non-compliant products may be initiated by CFIA. Actions may include further analysis to identify if there are potential health concerns, notification to the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

Of the cited references, one study by Cessna et al., (2002) reported an MRL exceedance in one out of a total of three flax seed samples from crops treated at 0.9 kg a.i./ha, even though glyphosate was reportedly used according to the registered use pattern. Specifically, a flax crop treated at a seed moisture content of 25% resulted in glyphosate residues at 3.27 ppm, thus slightly exceeding the Canadian MRL of 3 ppm for flax seed. To put this into context, 1.0 ppm is roughly equivalent to one granule in 273 cubes of sugar, or one drop of water in a bathtub. In light of this cited study, PMRA conducted a further dietary risk assessment using the residue value of 3.27 ppm in flax seed. It was also assumed that all flax seed consumed would have this level of residue, despite the exceedance being found in one sample only, in this one study. Even with this conservative assumption, the risk assessment did not change; the contribution to both the chronic and acute risks was less than 1% of the acceptable daily intake (ADI [e]) and less than 1% of the acute reference dose (ARfD[f]), respectively, and therefore not a health concern. Hence, a single MRL exceedance on its own, when considered with all reliable information available and

[d] **Good Agricultural Practice (GAP)** refers to the approved conditions of use on the label to achieve pest control.
[e] The acceptable daily intake (ADI) is the amount of pesticide residues a person may ingest from food and drinking water every day over a long-term period (up to lifetime) with no adverse effects
[f] The acute reference dose (ARfD)is the amount of pesticide residues a person may ingest from food and drinking water on a single day with no adverse effects

considered by the PMRA, does not present uncertainty that dietary risk from glyphosate is of health concern. It is also noteworthy that overall compliance with glyphosate MRLs has been shown to be very high (see the section below on CFIA monitoring data).

The 2015-2016 data analyzed in the 2017 Mitra report is a subset of the CFIA glyphosate monitoring data from 2015-2017. CFIA's analysis of the complete set of monitoring data from 2015-2017, reported 3 of 137 chickpea samples (data not reported by Mitra), or 2%, as having MRL exceedances, whereas none of the 100 wheat bran samples were in violation (Kolakowski et al., 2020). Note that although Kolakowski et al., (2020) was published after the publication of the RVD, given the redetermination of the Notice of Objection in accordance with the order of the Federal Court of Appeal, this article is included here to provide an updated and complete picture of the full data set, as the PMRA conducted a health risk assessment on all exceedances. This article identified that the highest glyphosate residues were found in chickpea flour (4.14 ppm to 12.5 ppm vs the MRL of 4 ppm in 3 non-compliant samples out of 57 samples) and in flour and dried forms of other beans (8.24 ppm and 8.6 ppm vs the MRL of 4 ppm in 2 non-compliant samples out of 169 samples). These exceedances were subject to a human health risk assessment by PMRA, and no health concerns were identified. More specifically, the PMRA used the highest level of 12.5 ppm in chickpea flour and the highest level found in other beans (8.6 ppm) to represent the residue for **all** chickpea and bean commodities, which is a highly conservative assumption. These residue levels are in contrast to the 5 ppm US tolerance for beans (which includes chickpeas) that PMRA used in the dietary risk assessment conducted for the glyphosate re-evaluation (Note: PMRA used the higher US tolerance of 5 ppm rather than the Canadian MRL of 4 ppm in the re-evaluation, to be protective). Even with the higher residue levels for chickpea and other bean commodities, the overall **contribution** to both acute and chronic dietary risk, was less than 1% of the ARfD or the ADI for most population subgroups, and the overall dietary risk was not a concern (12 – 45% of the ARfD for all population subgroups and 20 – 70% of the ADI for all population subgroups).

As demonstrated in the above examples, exceedance of an MRL in/on a food does not equate to health risk of concern, as MRLs for glyphosate are set at a level that is well below the level that could pose risk to humans. Furthermore, the monitoring data show that only a very small proportion of samples tested by the CFIA had residues of glyphosate above MRLs and that none of them were of health concern. CFIA's surveillance data is one of the tools that PMRA routinely uses in monitoring and assessing dietary risk for pesticides, and no health risks of concern have been identified to date for glyphosate. Given that the data analysis in the Mitra report was inaccurate and therefore scientifically unacceptable, and given that the PMRA considered the information in both the interim (2015-16) CFIA report and the article by Kolakowski et al., (2020) in the dietary risk assessment, which showed no health concerns, the information submitted in the Notice of Objection does not present any uncertainty in any aspect of the evaluation.

In summary, although this objection is directly linked to the evaluation of the pest control product, certain assumptions made in the objection are incorrect, some of the information was not scientifically reliable and regardless, the information or similar information provided in support of this objection had already been considered in the evaluation. Furthermore, the evidence provided in support of this objection, when considered with all scientifically reliable information available and considered by PMRA at the time of the decision, does not raise any uncertainty in any aspect of the evaluation. As a result, there is no scientifically founded doubt that would warrant establishing a review panel on this basis.

Criterion 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?

The advice of expert scientists would not assist in addressing the subject matter of this objection regarding the pre-harvest use and MRLs as there is agreement among federal government regulatory scientists with respect to the evidence presented in this objection. The objection was reviewed by PMRA scientists not involved in the original re-evaluation of glyphosate, who determined that there is no evidence presented in the objection that would affect the outcome of the re-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**?

The area of science covered in this objection and re-evaluation is not new and the regulatory approach for the evaluation of herbicides is well established globally. The health risk assessment of glyphosate was done following the standard regulatory and risk assessment frameworks[g,h], which has been in place in Canada and other OECD countries for many years. Therefore, given that the science and the regulatory framework are not new, the PMRA has concluded that the advice of an external panel will not aid in the regulatory decision-making process.

c) Is there a 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?

Health Canada's conclusions on the regulatory acceptability of glyphosate regarding the pre-harvest use, MRLs, MRL exceedances, and dietary risk considerations are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally. Therefore, the advice of expert scientists will not assist in addressing the subject matter of the objection.

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[g] PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products
[h] Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks

Objection 2: "Evidence of Dietary Exposure to Glyphosate as a Desiccant Not Examined in PRVD2015-01"

Safe Food Matters Inc. stated that 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, and maintained that such an examination is necessary, particularly given the mechanisms by which MRLs can be exceeded in desiccated crops, and that data from the CFIA indicates that exceedances are occurring.

Criterion 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?

The arguments are linked to the evaluation of the pest control product but do not directly pertain to the registered uses of glyphosate which is for "pre-harvest use", not for use as a "desiccant". This objection appears to arise from the confusion in terminology for pre-harvest use versus desiccant, as explained in the answer to Objection 1 above. In PRVD2015-01, in Appendix V, page 99, under "Supervised residues trial studies" it states, "The data support a maximum seasonal rate of 6.2 kg ae/ha in pre-emergent applications and 0.9 kg ae/ha **in pre-harvest applications** for forage crops (PHI 3-7 days) and all other crops (PHI of 7-14 days)." As explained in the response to Objection 1, glyphosate is not registered as a desiccant on any crop in Canada, but is registered and used pre-harvest as an herbicide to kill green weed biomass present in the field and facilitate harvest. As noted above, this pre-harvest use was considered in the re-evaluation.

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?**

The information or similar information submitted in support of the objection that is associated with the pre-harvest use of glyphosate was previously considered in PRVD2015-01. Dietary exposure associated with all uses of glyphosate was considered in the dietary risk assessment conducted during the re-evaluation, which included the pre-harvest use on crops.

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

[i] **Reliable Science**: science that is credible and unbiased. . Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments.

As mentioned above in response to Objection 1, an exceedance of an MRL does not automatically equate to a health risk of concern. The exceedances noted in the CFIA glyphosate monitoring data from 2015-2017 were subject to a human health risk assessment by PMRA and no health concerns were identified. As such the evidence provided in this objection does not present uncertainty in any aspect of the health assessment.

This objection is not directly related to the registered uses of glyphosate and the pre-harvest uses of glyphosate were already considered in the re-evaluation of glyphosate. Furthermore, the scientific basis and evidence provided in support of this objection, when considered with all scientifically reliable information available and considered by PMRA at the time of the decision, does not raise any uncertainty in any aspect of the evaluation. As a result, there is no scientifically founded doubt that would warrant establishing a review panel on this basis.

Criterion 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?

The advice of expert scientists would not assist in addressing the subject matter of this objection regarding the pre-harvest use and MRLs as there is agreement among federal government regulatory scientists with respect to the evidence presented in this objection. The objections were reviewed by PMRA scientists not involved in the original re-evaluation of glyphosate, who determined that the information associated with the pre-harvest use of glyphosate was already considered in the dietary risk assessment conducted during the re-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**?

The area of science covered in this objection and re-evaluation is not new and the regulatory approach for the evaluation of herbicides is well established globally. The health risk assessment of glyphosate was done following the standard regulatory and risk assessment frameworks[j], which has been in place in Canada and other OECD countries for many years. Therefore, given that the science and the regulatory framework are not new, the PMRA has concluded that the advice of an external panel will not aid in the regulatory decision-making process.

c) Is there a 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?'

[j] Refer to footnotes g, h

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?

Health Canada's conclusions on the regulatory acceptability of glyphosate regarding the pre-harvest use, MRLs, MRL exceedances, and dietary risk considerations are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally. Therefore, the advice of expert scientists will not assist in addressing the subject matter of the objection.

Objection 3: "Evidence that Dietary Exposure of Desiccated Crops has Increased**"**

Safe Food Matters stated that they consider the data used by the PMRA (dated 1998) related to consumption of crops that may be treated with glyphosate outdated and insufficient for the purposes of re-evaluating glyphosate. The objector considered PMRA's assessment to be inadequate, given the dramatic increases in production and consumption levels of legumes that may be treated with glyphosate, citing that consumption of chickpeas has grown by 90% since 2010. Safe Food Matters indicated that current consumption levels should be considered by the PMRA.

Criterion 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?

Yes, this objection is 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?

The evidence supporting this objection was not directly considered in the re-evaluation. However, based on PMRA's extensive experience using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™) software, including analyses of periodic updates to this software, the conservatisms used in the glyphosate dietary assessment, and that the potential daily intake for each population subgroup was considerably lower than the acceptable daily intake, an updated version of DEEM-FCID was not expected to affect the outcome of the health risk assessment of glyphosate.[k]

[k] As part of the assessment for the proposed maximum residue limit set out in PMRL2021-10, Glyphosate, an updated dietary assessment for glyphosate was conducted using the most recent version of DEEM software available at that time. No significant changes were noted in the outcome, and the health risks were shown to be

Further, PMRA's dietary assessments consider the aggregate consumption of all potentially treated foods rather than a commodity-by-commodity assessment alone. As such, changes in the dietary preferences of a single commodity is not expected to result in an underestimate of dietary intake when the full diet is considered. These points are explained in more detail below.

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

The basis of the objection is on an aspect of the evaluation conducted with respect to the health risks of the product. Safe Food Matters Inc. expressed concern regarding PMRA's use of *Continuing Surveys of Food Intakes by Individuals* (CSFII) 1994-1996 and 1998, and United States WWEIA (What We Eat in America) consumption data to assess dietary risk in the re-evaluation of glyphosate. Safe Food Matters Inc. argued that a dietary risk assessment using these data are inadequate because of the evidence that current levels of consumption and production of desiccated legumes like chickpeas and lentils has increased dramatically. Accurate numbers showing the increase in consumption would increase the numbers for the calculations of glyphosate exposure through diet.

PMRA's dietary exposure assessments (for new actives and re-evaluations, such as for glyphosate) rely upon the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™) and use the most recent version available at the time of the assessment. The PMRA commenced the re-evaluation of glyphosate in November 2009, and the dietary assessment was completed on August 2, 2013. The most up-to-date version of the DEEM-FCID™ program at that time (Version 2.14), incorporated consumption data from US Department of Agriculture (USDA)'s Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998.

The newer version of the DEEM-FCID™ software became available in the fall of 2013, which uses food consumption data from the United States' National Health and Nutritional Examination Survey, What We Eat in America (NHANES/ WWEIA) from 2005 to 2010. As part of the transition from CFII to NHANES/WWEIA, the PMRA compared the exposures from the consumption data from CSFII and NHANES/WWEIA, which showed that there were no significant differences in exposure between these two versions. In addition, an analysis of Canadian dietary consumption data from the Canadian Community Health Survey (CCHS, 2004) and American consumption data from NHANES/WWEIA also showed no significant differences. The NHANES/WWEIA data were adopted by the PMRA primarily due to its larger sample size, the fact that it is a continuous survey and that it represents the most recent food consumption data available (SPN2014-01). As such, even in more recent versions of DEEM with updated consumption data, dietary exposure is not expected to be of concern. As NHANES/WWEIA is a continuous survey, new consumption data representative of the food habits and trends are being collected

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acceptable. Given the redetermination of the Notice of Objection in accordance with the order of the Federal Court of Appeal, this information is included here to provide the updated and complete information concerning this objection.

[l] **Reliable Science**: science that is credible and unbiased. . Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments.

yearly and incorporated in the DEEM software with each new release. As updates to DEEM become available, PMRA applies the information to new assessments on a moving forward basis.[m]

It is also important to note that the residue input in DEEM is not directly related to each use scenario of the pesticide. Rather, if a pesticide is registered for several different use scenarios (e.g., pre-emergent use, early post-emergent use and pre-harvest use), then the residue level input in DEEM (a single value in ppm) is that of the **highest** residue observed among all the scenarios tested. Therefore, if the pre-harvest use results in the highest residue levels, it will be assumed that **all** legume crops that are consumed contain residues at levels expected from pre-harvest use. This is a highly conservative assumption. In addition, the dietary risk assessment conducted for the glyphosate re-evaluation assumed 100% of registered crops to be treated, which is also a very conservative assumption. These assumptions are designed to help ensure the assessment is protective of any potential dietary risks.

The Notice of Objection referenced data from the US pulse production from 2011 to 2016 (Bond 2017) and Canadian principal field crop supply and disposition from 2010 to 2016 from Statistics Canada. Projected rather than actual values for 2017 and 2018 were also presented. The US data showed pulse production increasing from approximately 2.8 billion pounds (2011/12) to 5 billion pounds (2015/16), a 1.8-fold increase. The Canadian data reported total domestic consumption of pulses and special crops increasing from 769,000 metric tonnes (2010-2011) to 1,968,000 metric tonnes (2015-2016), which is a 2.5-fold increase. The Notice of Objection argued that this increase of consumption of pulses and special crops, particularly those subject to pre-harvest use of glyphosate, is evidence and data that are required for an accurate current assessment of glyphosate. It also claimed that the dietary risk assessment conducted for the re-evaluation of glyphosate is inadequate from an evidentiary perspective because it did not consider the evidence that current levels of consumption and production of legumes like chickpeas and lentils, which can be treated pre-harvest, has increased dramatically. As such, accurate numbers showing the increase in consumption would increase the glyphosate exposure estimates through diet.

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 exposure for the following reasons:

1) The critical commodity analysis of the dietary exposure assessment conducted for the glyphosate re-evaluation, which identifies the specific food commodities that contribute the most to the dietary exposure, showed that no food commodity from pulse crops contributed more than 1% of the total exposure for any population subgroup. However, even if pulse crop consumption increased substantially, because the current dietary exposure estimates are based on highly conservative assumptions, exposure would still be well within acceptable levels (see below).
2) As reported in the consultation document (PRVD2015-01), the dietary exposure estimates (i.e., potential daily intake for each population subgroup)) 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. Thus, a considerable portion of these reference values remains ‘available’ before any exposure concerns would be identified.

Although a newer version of the DEEM software, using more recent food surveys, was released before the PMRA’s 2017 final Re-evaluation Decision, the PMRA did not change the assessment model mid-stream during the glyphosate re-evaluation, since it is PMRA’s practice to not change the methodology

[m] Refer to footnote k where an updated dietary assessment for glyphosate was done for a proposed maximum residue limit.

used in conducting the risk assessment that was presented in the consultation document (PRVD2015-01) and, as in the case of glyphosate, there were no health risk concerns based on a highly conservative (i.e., Tier I[n]) risk assessment.

The production and consumption figures provided do not raise any concerns with regard to the health risks associated with eating all foods that may be treated with glyphosate, including pulses.

Although the evidence supporting this objection has not been considered in the re-evaluation, it is not expected to affect the outcome of the health risk assessment of glyphosate. Dietary exposure would still be well within acceptable levels even if pulse crop consumption has increased substantially, as the risk assessment showed that no food commodity from pulse crops contributed more than 1% of the total exposure for any population subgroup.

In conclusion, the basis of this objection is on an aspect of the evaluation conducted with respect to the health risks of the product. Although the evidence supporting this objection was not considered in the re-evaluation, when considered with all scientifically reliable information considered by the PMRA at the time of the decision, it does not present uncertainty regarding the health evaluation. Therefore, Objection 3 does not raise a scientifically founded doubt as to the validity of the human health risk assessment conducted during the re-evaluation.

Criterion 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?**

The advice of expert scientists would not assist in addressing the subject matter of this objection regarding the dietary exposure from the consumption of crops that may be treated with glyphosate, as there is agreement among federal government regulatory scientists with respect to the evidence presented in this objection. This objection was reviewed by PMRA scientists not involved in the original re-evaluation of glyphosate, who determined that the 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.

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**?

The area of science covered in this objection and the re-evaluation is not new and the regulatory approach for the evaluation of herbicides is well established globally. The health risk assessment of glyphosate was done following the standard regulatory and risk assessment frameworks[o], which has been in place in Canada and other OECD countries for many years. Therefore, given that the science and the regulatory framework are not new, the PMRA has concluded that the advice of an external panel will not aid in the regulatory decision-making process.

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[n] Refer to paragraph 2, Criterion 1(c)for examples of conservative assumptions used
[o] Refer to footnotes g, h

c) Is there a 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?

Health Canada's conclusions on the regulatory acceptability of glyphosate regarding the dietary risk from the consumption of crops that may be treated with glyphosate are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally[pq]. Therefore, the advice of expert scientists will not assist in addressing the subject matter of the objection.

Objection 4: "MRLs for Unregistered Products Have Not Been Set as Required by the *Act*"

Safe Food Matters Inc. referenced the 2017 Guide to Crop Protection published by the Saskatchewan Ministry of Agriculture, which stated that the use of glyphosate for "Crop Staging for Pre-harvest Applications" on the crops canary seed, mustard, chickpea, lupin and faba bean is registered under the URMULE program, and because of this "the manufacturer assumes no responsibility for herbicide performance. Those who apply glyphosate to chickpea, lupin, faba bean, canary seed, camelina or mustard do so at their own risk."

Safe Food Matters Inc. claimed that there was no indication in the re-evaluation of glyphosate that the use of desiccation/ pre-harvest management on these additional crops has been assessed for health risks or that MRLs have been established for these crops subject to this use.

Criterion 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?

Yes, the basis of the objection is on an aspect of the health risk assessment

b) Was the evidence supporting the objection considered in the evaluation?

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[p] Status of glyphosate in the EU, https://food.ec.europa.eu/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en

[q] ECHA.Europa.eu classification of glyphosate, https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa

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?**

The Notice of Objection cited sections 9, 10 and 11 of the *PCPA*, and stated that section 10 applies to User Requested Minor Use Label Expansions (URMULEs). However, URMULEs are for Canadian registered uses of registered products, and as such, sections 9 and 11 of the *PCPA* apply to URMULEs, not section 10.

The claim in this objection that PMRA did not include the crops that had previously been registered under the URMULE is incorrect; those were considered in the evaluation (PRVD2015-01, Appendix IIa Registered Commercial Class Uses of Glyphosate in Canada as of 3 May 2012, page 65) as explained in the section below.

The *2017 Guide to Crop Protection published by the Saskatchewan Ministry of Agriculture* contains factual information about how these uses were registered and the registrant's 'user liability' statement. The user liability statement is not relevant to the human health risk evaluation. It is the choice of the registrant to include these statements on its marketplace label.

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

URMULE submissions were previously reviewed by the PMRA to assess the health risk from glyphosate residues that may result from pre-harvest use on camelina (sub no. 2010-6219), pearl millet (sub no. 2009-2317), canary seed (sub no. 2014-5021), mustard (sub no. 2010-1153), chickpea (sub nos. 2015-1580 and 2005-2797), and lupin and faba bean (sub no. 2005-2797). As there were no health risks of concern, these uses were registered and added to the MONSANTO ROUNDUP WeatherMax with Transorb 2 Technology Liquid Herbicide (registration number 27487) label at various times, upon completion of the respective submission reviews (i.e., residues in food commodities resulting from the pre-harvest use of glyphosate on these crops were determined to not pose health risks of concern to any segment of the population, including infants, children, adults and seniors).

Section 9 of the *PCPA* states that "When making a decision regarding the registration of a pest control product, the Minister shall, if necessary, specify any maximum residue limits for the product or for its components or derivatives that the Minister considers appropriate in the circumstances." Given that the use on pearl millet grain is for animal feed only, an MRL was not established for this commodity, as

[r] **Reliable Science**: science that is credible and unbiased. . Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments.

PMRA does not specify MRLs for animal feed. In addition, an MRL was not established for canary seed since, at the time of registration, canary seed was not considered a food use.

For camelina, mustard, chickpea, lupin and faba bean, the internationally recognized principle of crop grouping[s,t] was used for the purposes of establishing MRLs, which is described below.

Crop groupings are used in many countries around the world, including Canada, and allow for crop field trial residue data on a "representative" crop to be extended or used as a proxy for other crops within the same crop group. A crop group or subgroup is comprised of crops that are similar in terms of crop morphology (physical characteristics of the crop); growth habits; and the part of the crop that is edible (e.g., the beans inside the bean pods of bean plants). From all the crops listed in a crop group, between two and seven crops are chosen to be representative of the entire group, which are:

a) most likely to contain the highest pesticide residues (based on both supporting data and professional expertise), and
b) most likely to be a major crop in terms of production and/or consumption.

As all crops within a crop group have a similar plant structure and the same part of the crop is eaten, it is expected that pesticide residues for the representative crop will be the same or higher than residues for all other crops within the group when the pesticide is applied the same way.

MRLs are specified under the *PCPA* for gold of pleasure seeds (camelina) and mustard seeds (condiment type and oilseed type) at 10 ppm, based on residue data for canola, the representative crop for rapeseeds (crop subgroup 20A).

Glyphosate was registered for pre-harvest use on beans (including chickpea, lupin and faba bean) in 1992, based on field trial studies for "white bean", which is the former industry terminology for dry common beans. An MRL of 4 ppm was established on beans as a result of this registered use. Between 2005 and 2015, the PMRA received URMULE submissions to support the use of glyphosate on a variety of specific beans including chickpea, lupin and faba bean, to further clarify the "bean" use on the label. As mentioned above, the PMRA assessed the health risk from the glyphosate residues in/on these specific beans under the URMULE submissions. Therefore, as previously noted, the existing MRL of 4 ppm for beans also applies to chickpea, dried lupin, and dried faba bean, since residues on these crops fall into the same crop group. There has been no evidence that the MRL of 4 ppm for the bean crop group is not representative of the residues found on chickpeas, dried lupin and dried faba bean or resulted in exceedances. CFIA monitoring data, which are actual residues taken from crops, have shown that the vast majority of these specific crops have actual residue levels below the established MRL.

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[s] Crop Grouping – IR-4 Project

[t] Codex Classification of Foods and Animal Feeds | Agrisemantics Map of Data Standards
The **Codex Classification of Foods and Feeds** is intended primarily to ensure the use of uniform nomenclature and secondarily to classify foods into groups and/or sub-groups for the purpose of establishing group maximum residue limits for commodities with similar characteristics and residue potential.
www.fao.org/input/download/standards/41/CXA_004_1993e.pdf

Although, this objection is directly linked to the evaluation of the pest control product, as mentioned in the response to the previous objection above, the dietary risk assessment conducted during the re-evaluation encompasses all registered food uses, including all registered pre-harvest uses on food crops such as camelina, mustard, chickpea, lupin and faba bean, and did not identify a health concern. The objection does not raise scientifically founded doubt as to the validity of the evaluation as the uses were already considered in the assessment, and there is no uncertainty in any aspect of the evaluation.

Criterion 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?

The advice of expert scientists would not assist in addressing the subject matter of this objection regarding the pre-harvest uses of glyphosate registered under the URMULE program as there is agreement among federal government regulatory scientists that the evidence presented in this objection, i.e. the 2017 Guide noted earlier, was not relevant to the human health risk assessment, and that the internationally recognized principle of crop grouping[u] was used for the purposes of establishing and verifying MRLs for camelina, mustard, chickpea, lupin and faba bean in 1992 and between 2005 - 2015.

The objections were reviewed by PMRA scientists not involved in the original re-evaluation of glyphosate, who determined that the various crops associated with the pre-harvest uses of glyphosate registered under the URMULE program were already considered in the risk assessment conducted during the re-evaluation and were assessed previously under the URMULE program.

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**?

The area of science covered in this objection and re-evaluation is not new and the regulatory approach for the evaluation of herbicides is well established globally. The health risk assessment of glyphosate was done following the standard regulatory and risk assessment frameworks[v], which has been in place in Canada and other OECD countries for many years. Therefore, given that the science and the regulatory framework are not new, the PMRA has concluded that the advice of an external panel will not aid in the regulatory decision-making process.

c) Is there a 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?'

[u] Refer to footnotes q, r
[v] Refer to footnotes g, h.

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?

Health Canada's conclusions on the regulatory acceptability of glyphosate regarding the pre-harvest uses of glyphosate registered under the URMULE program are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally. Therefore, the advice of expert scientists will not assist in addressing the subject matter of the objection.

Objection 5: "Label Amendments Don't Address Risk"

Safe Food Matters Inc. states that the risk to human health from consuming crops that have been desiccated with glyphosate when moisture content is high is not mitigated by the proposed label amendments from the re-evaluation. It argues that there is no reasonable certainty that no harm to human health or future generations will result from dietary exposure to glyphosate, given that

1) *no label statements were proposed that would mitigate risk to human health from desiccation, and*
2) *any such label statements would not with reasonable certainty be effective due to the following:*
    a. *visual indicators of moisture content in the plant are subjective,*
    b. *the different stages of maturity in indeterminate plants such as pulse crops, and*
    c. *the unpredictability of the weather which can affect moisture content.*

Criterion 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?

Yes, this objection is directly linked to the evaluation of the pest control product and label mitigation measures that determine how a product may be used according to the conditions of registration.

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?

There was no scientific data provided in support of this objection that was not considered during the re-evaluation.

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

The labels are explicit that pre-harvest applications must be done when grain moisture is less than 30% as part of the directions of use. The visual indicators on the labels provide additional guidance in terms of how to determine when that moisture threshold is reached. Applications to crops with greater than 30% moisture content in the grain would be inconsistent with the label directions and, as such, a contravention under the PCPA. It should also be noted that it is relatively simple for growers to take a small sample of the grain and have it quickly tested for moisture content to ensure that the timing of pre-harvest applications is correct[x].

As described in the responses to Objections #1-4 above, the residue data used to establish MRLs were based on this specific pre-harvest use pattern. The resulting MRLs were then used to conduct the dietary risk assessment for the glyphosate re-evaluation, which did not identify any health risks of concern.

It is acknowledged that some pulse crops have an indeterminate growth characteristic, which leads to continuous seed production and "mature pods at the bottom of the plant and greener material at the top" (Brenzil 2012). This may result in application of glyphosate to crops that have seed at the top that are higher in moisture content than the seed at the bottom. However, since the seed at the top would not be fully mature at the point of harvest, this seed would not be marketable. Furthermore, there are strict standards by the Canadian Grain Commission that must be respected for pulses to ensure the quality of seed; as such, the immature seeds would not be allowed to enter commercial channels.

In addition to the fact that growers must follow the directions of use on the label, it should also be noted that it is not in the best interest of growers to use a pre-harvest application of glyphosate when grain moisture content is greater than 30%, since incorrect timing of pre-harvest herbicides can

a) have a negative impact on crop maturity;
b) interrupt the process of seed filling, resulting in yield loss; and
c) as mentioned by the objector, result in more herbicide residue in the seed (Brenzil 2012).

Overall, the scientific basis for the objection is linked to the evaluation of the pest control product pest control products and label mitigations, but there was no scientific data provided in support of this objection that was not considered during the re-evaluation. The information provided, when considered with all scientifically reliable information available at the time of the decision, does not present uncertainty regarding any aspect of the health assessment and, therefore, no scientifically founded doubt has been raised so as to warrant establishing a review panel.

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

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[w] **Reliable Science**: science that is credible and unbiased. . Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments.

[x] Grain moisture can be tested at grain elevators or by individual growers using a grain moisture meter which is a simple and fast test for moisture content.

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?**

The advice of expert scientists would not assist in addressing the subject matter of this objection regarding the label mitigation measures for glyphosate products as there is agreement among federal government regulatory scientists that the evidence presented in this objection would not affect the outcome of the evaluation. The objections were reviewed by PMRA scientists not involved in the original re-evaluation of glyphosate, who determined that the information associated with the pre-harvest use of glyphosate was already considered in the health risk assessment conducted during the re-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**?

The area of science covered in this objection and re-evaluation is not new and the regulatory approach for the evaluation of herbicides is well established globally. The health risk assessment of glyphosate was done following the standard regulatory and risk assessment frameworks[y], which has been in place in Canada and other OECD countries for many years. Therefore, given that the science and the regulatory framework are not new, the PMRA has concluded that the advice of an external panel will not aid in the regulatory decision-making process.

c) **Is there a 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?**

Health Canada's conclusions on the regulatory acceptability of glyphosate taking into account the label mitigation measures for glyphosate products are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally. Therefore, the advice of expert scientists will not assist in addressing the subject matter of the objection.

Objection 6: "No Consideration of Whether Labels are Followed",
Objection 7: "Enforcement of Any Imposed Label Requirements on Desiccants Not Likely"
Objection 8: "Unlikely that Following Labels Will Bring No Harm, since Statutory Regime Contemplates Exceedances of MRLs Even When Labels are Followed"

Safe Food Matters Inc. presented three concerns regarding the effectiveness of labelling and label enforcement: a) citing the percentage of non-compliance according to PMRA's 2015-2016 Compliance

[y] Refer to footnotes g, h.

and Enforcement Report; b) arguing that enforcement of any requirements regarding moisture content on the labels would be practically and administratively difficult, thus requirements would be unlikely followed; and c) presenting the possibility of MRLs being exceeded even when labels are followed, thus it is uncertain that no harm will result from glyphosate exposure.

These objections are directed towards potential enforcement issues related to the conditions specified on the label, which are legal requirements of registration.
These objections are outside the scope of the Notice of Objection process, which is science-based in accordance with the PCPA and section 2 of the *Review Panel Regulations*.

There are specific regulatory mechanisms by which compliance with labelling for pest control products is enforced. For example, it is an offence under the *PCPA* if a pest control product such as glyphosate is not used in accordance with the label directions. The Regulatory Operations and Enforcement Branch of Health Canada monitors compliance through inspections and compliance programs that investigate adherence to pesticide label directions. Furthermore, as described previously, the CFIA monitors pesticide residue levels in food commodities and reports MRL exceedances to the PMRA, which are assessed for health risks and subsequent follow up action by CFIA, as warranted. With respect to Objection #8, the few glyphosate MRL exceedances identified to date and discussed above in PMRA's response to Objection #1 have been assessed by PMRA scientists and no risks of concern to Canadians was found. Glyphosate exposure via residues in the diet is well within acceptable levels.

Regarding concerns on the effectiveness and enforcement of labelling set out in Objections #6 and #7, no scientific basis to the objections and no new evidence to support the objections, including scientific data or test data, were provided in support of these objections.

In conclusion, these three objections are not science-based and therefore do not meet the requirements under subsection 2(c) of the *Regulations*. As such, there is no basis on which the Minister could consider the factors for establishing a review panel set out in section 3 of the *Regulations,* i.e., whether there is scientifically founded doubt as to the validity of the evaluations, on which the decision was based, and whether the advice of expert scientists would assist in addressing these three objections.

Objection 9: "Reductions of Safety Factor Without Scientific Rationale"

Safe Food Matters objected to reductions of the PCPA safety factor from 10-fold to 1-fold for most populations and to 3-fold for the ARfD for females 13 – 49 years of age, asserting there was no scientific rationale with regards to the serious endpoint of cardiovascular malformations in the rabbit developmental toxicity study. Safe Food Matters indicated that the tempering of the concern surrounding the "serious endpoint" based on the presence of maternal toxicity does not appear to be permitted, based on the approach outlined in SPN2008-01.

Safe Food Matters Inc. referenced the aggregate risk assessment in PRVD2015-01 conducted for children 1 to less than 2 years old, that examined dermal exposure to glyphosate along with incidental oral exposure (hand-to-mouth) from contact with treated lawns/turf in conjunction with chronic dietary exposure (food and drinking water). Based on information in PRVD2015-01 Safe Food Matters Inc. noted that this aggregate exposure scenario initially assumed a glyphosate application rate of two applications with a seven-day interval. At that application rate, the aggregate Margins of Exposure (MOE) for children (1 to less than 2 years old) did not reach the target of 100, citing PMRA's conclusion: "Therefore, refinements to the risk assessment were required".

Safe Food Matters Inc. claimed that in response to this finding, PMRA changed the aggregate assessment without a reliable scientific rationale, to one application of glyphosate with a seven-day time-weighted turf transferable residue average for the entire aggregate assessment for all populations. The average residues of glyphosate were calculated over a seven-day span, rather than assuming exposure to residues immediately after application. In addition, Safe Food Matters Inc. stated that this refinement of the aggregate risk assessment in effect reduced the 10-fold safety factor by changing the application rates, since the 10-fold factor would have been exceeded had the application rates stayed the same.

Criterion 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?

Yes, this objection is 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?

The objector did not provide evidence supporting the objection but rather, proposed a different approach to the refinement of the aggregate assessment. The detailed explanation of the PMRA approach is provided below.

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

PCPA Factor reduction:
Safe Food Matters Inc.'s objection to reduction of the *PCPA* safety factor from 10-fold to 1-fold for most populations and to 3-fold for the ARfD for females 13 – 49 years of age appears to be based on the objector's interpretation of SPN2008-01[aa], the PMRA's Science Policy Note that describes how the PMRA applies the *PCPA* safety factor. The PMRA published a draft document for consultation, held two

[z] **Reliable Science**: science that is credible and unbiased. . Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments.

[aa] PMRA (Pest Management Regulatory Agency), 2008, Science Policy Note (SPN2008-01): The Application of Uncertainty Factors and the *Pest Control Products Act* Factor in the Human Health Risk Assessment of Pesticide. Available online from http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2008-01/index-eng.php [Last accessed May, 2022]

stakeholder workshops, and received comments from expert scientists prior to finalizing this science policy document.

SPN2008-01 explains that there are different uncertainty factors, sometimes referred to as safety factors, which are considered when determining the Acceptable Daily Intake (ADI) and the Acute Reference Dose (ARfD), the dietary reference values that are then used in risk assessment. First, there is a standard uncertainty (safety) factor of 100-fold to account for extrapolating data between animals and humans, as well as to account for the variability between humans. Second, the Act requires that a factor of 10-fold, known as the PCPA factor, be applied in accordance with s. 19(2)(b)(ii). Science Policy Note 2008-01 provides guidance on the application of the PCPA factor. The overall safety factor, ranging from 100 to 1000-fold, is the division factor that the PMRA uses when calculating the ADI and ARfD for humans. As described above, the PMRA sets the reference values at a minimum of 100-fold less than the maximum dose that has been observed to cause no harmful effects in animals.

There are circumstances that allow the PMRA to reduce or remove the 10-fold PCPA factor, as permitted by the Act and reflected in the Science Policy Note. In the case of glyphosate, the PMRA reduced the PCPA factor to 1-fold to set the ADI for the chronic dietary assessment. For the population subgroup females of child-bearing age 13-49 years, the PCPA factor was reduced to 3-fold for the acute dietary assessment (the ARfD for females 13-49 years). That is, the ADI was set at 100-fold less, while the ARfD was set to 300-fold less for females (13-49 years), and 100-fold less for the general population, relative to the dose that caused no harmful effects in animals. The rationale for the PMRA's choice of safety factors was provided in PRVD2015-01 (page 17) and in RVD2017-01 (page 27-28).

To summarize the above, generally, before any potential adjustments are applied under section 19(2)(b)(iii), the reference level for acceptable human exposure to a pesticide is typically set at 100-fold less than the amount which has been found to cause no harmful effect in animals. Where the PCPA Factor is applied, the reference level for acceptable exposure increases up to 10-fold, that is, it is set up to 1000-fold less than the level of exposure found to cause no harmful effect in animals.

While SPN2008-01 does not list all possible situations where a level of concern may be reduced, this scenario is addressed by the first paragraph of Section 4.1 of SPN2008-01:

> Under the new *PCPA*, the PMRA must apply a default 10-fold factor (the *PCPA* factor) unless the PMRA concludes, based on reliable data, that a different factor is appropriate for the protection of infants and children. Determination of the magnitude of the factor involves evaluating the completeness of the data with respect to exposure of and toxicity to infants and children as well as potential for prenatal or postnatal toxicity (see Figure 2 of SPN2008-01). Incomplete toxicology databases are not equally incomplete and all prenatal and postnatal toxicities are not of equal concern. For these reasons, the PMRA makes specific case-by-case determinations as to the size of the *PCPA* factor if reliable data permit. An integrative approach is taken to optimize use of all available information. A *PCPA* factor less than or equal to 10-fold or, in very rare circumstances, greater than 10-fold may be employed in an assessment. Given the extensive data typically available for a given pesticide, the PMRA believes that in most instances, there will be sufficient reliable data to conduct an individualized assessment of the factor necessary to assure the safety of infants and children.

In determining whether to reduce the *PCPA* factor, PMRA considers contextual information. 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, and therefore toxicity, in some instances. Having regard to the data, and considering the completeness of the data along with potential effects on vulnerable populations, PMRA found the PCPA Factor could be reduced. Decreased maternal body weight or body weight gain at sensitive stages of development can result in changes in the fetus independent of direct chemical harm to the fetus. A *PCPA* factor of 10-fold is retained where serious effects are observed in the fetus at doses that do not adversely affect the maternal animal.[bb]

Concerns were raised in this objection regarding PMRA's reduction of the 10-fold PCPA Factor to 3-fold in setting the ARfD for females 13-49 years, even though fetal malformations were observed in one rabbit developmental toxicity study. Amongst nine (9) developmental and reproductive toxicity studies in rats and rabbits that were reviewed[cc], only one study had any evidence of fetal toxicity at the maternal lowest adverse effect level (LOAEL). In other studies, offspring effects typically occurred at higher doses than doses that caused effects in maternal animals. As effects in this one study were observed at a maternally toxic dose, the PMRA considered the PCPA factor in a manner consistent with SPN2008-01 and other PMRA evaluations, reducing it to 3-fold when setting the ARfD for females 13-49 years, resulting in an ARfD that was 300-fold less than the dose that caused no harmful effects in animals.

Aggregate Assessment:
As noted above, the objection took issue with PMRA's approach to the aggregate assessment. In determining the approach to conducting the aggregate risk assessment for children aged 1 to less than 2 years old, who may be exposed to glyphosate, PMRA followed the method described in Science Policy Note SPN2003-04: *General Principles for Performing Aggregate Exposure and Risk Assessments*.

As described in PRVD2015-01, in the initial risk assessment for children aged 1 to less than 2 years old exposed to glyphosate, the target Margin of Exposure (MOE) of 100 was not reached when aggregating chronic dietary exposure (food and drinking water) and post-application exposure (dermal and incidental dietary) from entering turf treated with two applications, 7 days apart. This means that more realistic conditions, or refinements, of potential exposures should be examined, to determine if risks are acceptable (i.e., target MOEs are met) under more realistic scenarios. While aggregate assessment considers both dietary and non-dietary exposures occurring at the same time, as per SPN2003-04, the co-occurrence of high-end (worst-case) food, drinking water and residential exposure scenarios will often be impossible or, at best, highly unlikely. As such, the assumptions in the aggregate risk assessment were adjusted to represent a more realistic scenario, which included the following:

- For the dietary component of the aggregate assessment, Canadian MRLs instead of American tolerances/Codex MRLs for barley, oats and wheat were incorporated, since 99% of these crops consumed in Canada are produced in Canada[dd];
- A typical application pattern of only one application at the maximum application rate was used; and

[bb] PMRA's choice of safety factors was provided in PRVD2015-01 (page 17) and in RVD2017-01 (page 27-28).
[cc] Standard data requirements to assess potential effects on offspring for a pesticide active ingredient are: two (2) developmental toxicity studies and one (1) reproductive toxicity study, for a total of three (3) studies
[dd] The US cereal crop group tolerance is 30 ppm. Canadian glyphosate MRLs are 5 ppm for wheat, 10 ppm for barley and 15 ppm for oats. The US tolerances (MRLs) used in the initial assessment are much higher than Canadian MRLs, but only 1% of US crops are consumed in Canada. Therefore, more realistic assumptions were considered for aggregate assessment for children aged 1 to less than 2 years old.

- A 7-day time-weighted average turf transferrable residue value was applied.

Using the adjusted assumptions, the refined (i.e., more realistic) aggregate risk assessment for children aged 1 to less than 2 years old resulted in a calculated MOE that reached the target MOE of 100, indicating that aggregate risks were shown to be acceptable.

Although this objection is directly linked to the evaluation of the pest control product, the objector did not provide evidence supporting the objection but rather, had a different interpretation of the PMRA science policy document on the application of the PCPA Factor (SPN2008-01) as well as PMRA's approach to the refinement of the aggregate assessment. In the re-evaluation of glyphosate, the PMRA considered the PCPA factor in a manner consistent with SPN2008-01 and other PMRA evaluations, and applied principles similar to those applied in other regulatory jurisdictions. In particular, with respect to the rabbit study presented by SFM, the weight of evidence supports the conclusion that glyphosate levels that do not cause toxicity in maternal animals are not expected to cause toxicity in the offspring.

When considered with all scientifically reliable information available at the time of the decision, the objectors interpretation of PMRA's refinement of the aggregate assessment does not present uncertainty regarding how the PMRA applied the PCPA factor; which was consistent with SPN2008-01, other PMRA evaluations, and principles applied in other regulatory jurisdictions. As a result, there is no scientifically founded doubt has been raised so as to warrant establishing a review panel.

Criterion 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?

There is agreement among federal government regulatory scientists regarding the reductions to the PCPA Factor. This objection was reviewed independently by PMRA scientists not involved in the original re-evaluation of glyphosate, who determined that there is no information presented with respect to this objection that would 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**?

The health risk assessment of glyphosate was done following the standard regulatory framework[ee], which has been in place in Canada and other OECD countries for many years. Neither the science nor the regulatory framework used in the assessments are new.

c) Is there a 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?

[ee] Refer to footnotes g, h

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?**

Health Canada's conclusions on the regulatory acceptability of glyphosate based on its approach to the refinement of the aggregate assessment are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally that conduct aggregate assessments.

As noted above, the objector provided a different interpretation of SPN2008-01 but did not provide any evidence to support their objection. Given the consistency with other international scientific regulatory authorities, and that the *PCPA* factor applied in this assessment offers even more fetal protection relative to some other international jurisdictions, PMRA has concluded that the advice of an external panel will not assist in addressing the subject matter of the objection.

Overall Conclusion:
In summary, following careful examination of each of the objections raised in the Notice of Objection submitted by Mary Lou McDonald in her own capacity and in the capacity as the president of Safe Food Matters Inc. related to RVD2017-01, the PMRA has considered the factors set out in section 3 of the *Review Panel Regulations* and has concluded: (a) that the information provided in this Notice of Objection does not raise scientifically founded doubt as to the validity of the evaluations, on which the decision (RVD2017-01) was based, regarding the health risk assessment for glyphosate; and (b) that the advice of expert scientists would not assist in addressing the subject matter of the objection. As such, it is not necessary to establish a review panel to consider any of the objections raised in this Notice of Objection. As a consequence, this Notice of Objection is now closed.

Should you have any questions regarding this letter, please submit them to the Notice of Objection e-mail account (pmra.noo-ado.arla@hc-sc.gc.ca) and we will respond as soon as possible. Please quote Reference Number 2017-3047 in any correspondence regarding the Notice of Objection to the re-evaluation of glyphosate.

Sincerely,

For:
Frédéric Bissonnette
Chief Registrar
Pest Management Regulatory Agency

Reference list

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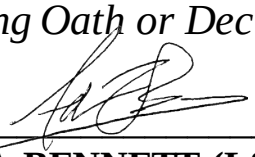
THIS IS **EXHIBIT "C"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

From: jason@gratlandcompany.com
Sent: December 20, 2022 9:33 PM
To: Kravchuk, Walter; jodi@gratlandcompany.com
Cc: toby@gratlandcompany.com; Zita-Bennett, Adrian; Hucal, Kathryn
Subject: RE: Safe Food Matters Inc. v AGC et al. (Federal Court file no. S-2292-22)
Attachments: Notice of Application (Amended) December 20, 2022.pdf

Hi Walter,

Further to my email below, please find a draft amended Notice of Application attached.

I expect to write to the Court tomorrow to request a Case Management Conference and/or seek directions regarding the process.

Could you please advise whether the Respondent consents to the amendment.

Best regards,

Jason

From: jason@gratlandcompany.com <jason@gratlandcompany.com>
Sent: December 5, 2022 4:21 PM
To: 'Kravchuk, Walter' <Walter.Kravchuk@justice.gc.ca>; 'jodi@gratlandcompany.com' <jodi@gratlandcompany.com>
Cc: 'toby@gratlandcompany.com' <toby@gratlandcompany.com>; 'Zita-Bennett, Adrian' <Adrian.Zita-Bennett@justice.gc.ca>; 'Hucal, Kathryn' <Kathryn.Hucal@justice.gc.ca>
Subject: RE: Safe Food Matters Inc. v AGC et al. (Federal Court file no. S-2292-22)

Hi Walter,

We will honour the agreements made by previous counsel. I will send a signed consent order to your office tomorrow (signed on my behalf).

Could you please send a copy of the draft CTR to my office, preferably by electronic means.

I should advise that I am in the process of finalizing some proposed amendments to the Notice of Application, principally to clarify that we will be putting the concept of regulatory capture and some of the history of PMRA forward as an interpretive aide to assist with the interpretation of when independent advice is advisable. I should have a draft Notice of Application to share with you by the end of the week.

Best regards,

Jason

From: Kravchuk, Walter <Walter.Kravchuk@justice.gc.ca>
Sent: December 5, 2022 3:03 PM
To: jodi@gratlandcompany.com
Cc: 'JBG G&C' <jason@gratlandcompany.com>; toby@gratlandcompany.com; Zita-Bennett, Adrian

<Adrian.Zita-Bennett@justice.gc.ca>; Hucal, Kathryn <Kathryn.Hucal@justice.gc.ca>
Subject: RE: Safe Food Matters Inc. v AGC et al. (Federal Court file no. S-2292-22)

Thank you, Jodi. Confirming receipt of the Notice of Change.
Ms. McDonald had requested a time extension to exchange affidavits. We then corresponded and agreed to extend virtually all of the litigation steps.

The first extended deadline is the transmission of the CTR. I attach a copy of my email to Ms. McDonald from Friday. I also attach a Word version of the Consent.
Please send us a dated / executed Consent in a fresh email.
Many thanks.

Walter

Walter Kravchuk
Counsel / Avocat
National Litigation Sector / Secteur National du Contentieux
Ontario Regional Office / Bureau Régional de l'Ontario
Department of Justice Canada / Ministère de la Justice Canada
120 Adelaide St. West, Suite 400 / 120, rue Adelaide Ouest, Pièce 400
Toronto, ON, M5H 1T1

Tel : 647.256.1659
E-mail : walter.kravchuk@justice.gc.ca

Canada

From: jodi@gratlandcompany.com <jodi@gratlandcompany.com>
Sent: Monday, December 5, 2022 5:03 PM
To: Kravchuk, Walter <Walter.Kravchuk@justice.gc.ca>; safefoodmatters@gmail.com
Cc: 'JBG G&C' <jason@gratlandcompany.com>; toby@gratlandcompany.com
Subject: Safe Food Matters Inc. v AGC et al. (Federal Court file no. S-2292-22)

Good afternoon,

Please find enclosed for service a Notice of Change of Solicitor in the above-noted matter.

Kindly confirm service by return email at your earliest convenience.

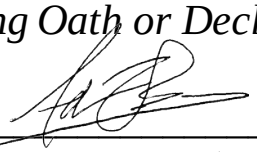
Kind Regards,

Jodi Kaldestad
Paralegal

Gratl & Company
Barristers and Solicitors
511-55 East Cordova Street
Vancouver, BC V6A 0A5
604-694-1919 (t)
604-608-1919 (f)
www.gratlandcompany.com

THIS IS **EXHIBIT "D"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

From:	jodi@gratlandcompany.com
Sent:	March 10, 2023 4:48 PM
To:	Kravchuk, Walter; Hucal, Kathryn
Cc:	jason@gratlandcompany.com; toby@gratlandcompany.com; Zita-Bennett, Adrian; Aydoner, Ezel (she; her | elle; la)
Subject:	RE: Safe Food Matters Inc. v AGC et al. (Fed Court File No. T-2292-22)
Attachments:	Amended Notice of Application.pdf

Good afternoon,

Further to the order of January 20, 2023 of Associate Judge Catherine Coughlan, please find enclosed for service the Amended Notice of Application of the Applicant in the above-noted matter.

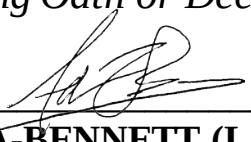
Kindly confirm service by return email.

Regards,
Jodi Kaldestad
Paralegal

Gratl & Company
Barristers and Solicitors
511-55 East Cordova Street
Vancouver, BC V6A 0A5
604-694-1919 (t)
604-608-1919 (f)
www.gratlandcompany.com

THIS IS **EXHIBIT "E"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Department of Justice Canada **Ministère de la Justice Canada**

Ontario Regional Office
National Litigation Sector
120 Adelaide Street West,
Suite 400
Toronto Ontario M5H 1T1
Canada

Région de l'Ontario
Secteur national du contentieux
120, rue Adelaide ouest, pièce 400
Toronto (Ontario) M5H 1T1

Telephone/Téléphone: (647) 256-1659
Email/Courriel: walter.kravchuk@justice.gc.ca

January 30, 2023

Our File Number: LEX-500112902

VIA E-MAIL [jason@gratlandcompany.com]

Mr. Jason Gratl
Gratl & Company
Barristers and Solicitors
511-55 Cordova St. E
Vancouver, BC
V6A 0A5

Dear Mr. Gratl:

Re: Safe Food Matters Inc. v. Attorney General of Canada and Minister of Health
Court File No. T-2292-22

It has come to my attention that, through inadvertence, Volume 2 of the CTR ("Inadvertently Disclosed Information") transmitted in these proceedings did not fully redact irrelevant and privileged information. This written notice shall be the Respondent's privilege notice to the Applicant in regards to the Inadvertently Disclosed Information ("Privilege Notice").The Applicant receiving this Privilege Notice shall:

a) delete any electronic information associated with the Inadvertently Disclosed Information anywhere in possession;

b) if any hard copies were made of the Inadvertently Disclosed Information, immediately destroy those hard copies;

c) agree not to make any use of the Inadvertently Disclosed Information;

d) advise all persons who may have been provided with an electronic or hard copy of the Inadvertently Disclosed Information not to make any use of it and to destroy any copies of

it. If they were provided with Inadvertently Disclosed Information on any storage device, then they shall return the device to the sender to be destroyed; and

e) provide written confirmation to the Respondent that the above steps, as applicable, have been completed within five (5) days of the delivery of the Privilege Notice.

In addition to the above request, we would require your consent to re-transmit Volume 2 of the CTR to the Registry together with a letter seeking an Informal Request. At your earliest opportunity, please confirm we have your consent. We would, of course, copy your office on any correspondence to the Court.

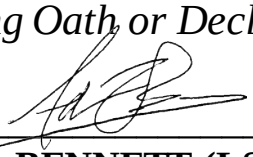
Thank you in advance for your cooperation.

Sincerely,

Walter Kravchuk
Counsel, National Litigation Sector
WK:ea

THIS IS **EXHIBIT "F"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Department of Justice Canada
Ministère de la Justice Canada

Ontario Regional Office
National Litigation Sector
120 Adelaide Street West Suite #400
Toronto, ON M5H 1T1

Région de l'Ontario
Secteur national du contentieux
120, rue Adelaide ouest, pièce 400
Toronto, ON M5H 1T1

Telephone/Téléphone: 416-526-2299
Fax/Télécopieur: 416-973-0809
Email/Courriel: Adrian.Zita-Bennett@justice.gc.ca

February 10, 2023

VIA ELECTRONIC FILING

Registry
Federal Court of Canada
Thomas D'Arcy McGee Building
90 Sparks Street, 1st Floor
Ottawa, ON
K1A 0H9

Dear Honourable Court:

Re: ***Safe Food Matters Inc v Attorney General of Canada and Minister of Health***
Court File No.: T-2292-22

I write on behalf of the Respondents, the Attorney General of Canada and Minister of Health (collectively, **"Canada"**), to request that the Chief Justice assign a Case Management Judge in the above-named matter, pursuant to Rules 383 and 384 of the *Federal Courts Rules*.

On October 31, 2022, the Applicant, Safe Food Matters Inc., commenced its application for judicial review of a reconsideration decision of the Pest Management Regulatory Agency (**"PMRA"**) concerning registration of the pesticide glyphosate, alleging this decision was unreasonable and procedurally unfair.

The PMRA transmitted the Certified Tribunal Record (**"CTR"**) to the Court on December 15, 2022. On January 19, 2023, the Applicant sought leave to file an Amended Notice of Application with Canada's consent, which was granted by way of Order of Associate Judge Coughlan, dated January 20, 2023. Soon thereafter, it came to Canada's attention that intended redactions in volume 2 of the CTR were not applied. On January 30, 2023, Canada sought consent from counsel for the Applicant, Mr. Gratl (copied), to fix this technological error and re-file the CTR. To date, Mr. Gratl has not provided his consent and has intimated that the package transmitted by the PMRA is incomplete.

Accordingly, pursuant to Rule 3, in the interest of securing the most expeditious, just, and least expensive outcome in terms of managing the procedural and substantive aspects of this proceeding, Canada requests that this matter be case-managed. The Applicant has consented to this request.

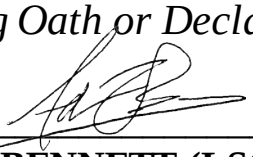
Yours truly,

Adrian Zita-Bennett
Counsel
National Litigation Sector

cc: Jason Gratl, Gratl & Company, jason@gratlandcompany.com
Counsel for the Applicant

THIS IS **EXHIBIT "G"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Federal Court Cour fédérale

Date: 20230210

Docket: T-2292-22

Toronto, Ontario, February 10, 2023

PRESENT: Associate Judge Trent Horne

BETWEEN:

SAFE FOOD MATTERS INC

Applicant

and

ATTORNEY GENERAL OF CANADA AND MINISTER OF HEALTH

Respondent

ORDER

UPON informal request by the respondents, by letter dated February 10, 2023, for an order that this application be specially managed, and that a case management judge be assigned;

AND UPON being advised that the applicant consents to the relief requested;

AND UPON being satisfied that this application would benefit from being specially managed, and from the appointment of a case management judge;

THIS COURT ORDERS that:

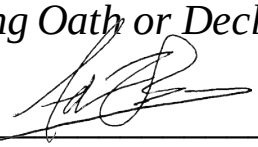
1. This application shall proceed as a specially managed proceeding and be referred to the Office of the Chief Justice for the appointment of a case management judge.

2. Within 10 (ten) days of the appointment of a case management judge, the parties shall write to the Court and provide a status update, a proposed timetable for the next steps in the proceeding, and dates and times of mutual availability for a case management teleconference.

"Trent Horne"
Associate Judge

THIS IS **EXHIBIT "H"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Federal Court Cour fédérale

Date: 20230221

Docket: T-2292-22

Ottawa, Ontario, February 21, 2023

PRESENT: The Chief Justice

BETWEEN:

SAFE FOOD MATTERS INC

Applicant

and

ATTORNEY GENERAL OF CANADA
AND MINISTER OF HEALTH

Respondent

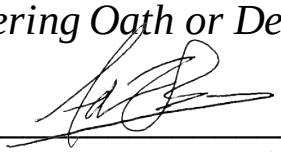
ORDER

IT IS ORDERED pursuant to Rule 383 that Associate Judge Benoit M. Duchesne is assigned as Case Management Judge in this matter.

"Paul S. Crampton"
Chief Justice

THIS IS **EXHIBIT "I"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

GRATL & COMPANY

BARRISTERS AND SOLICITORS

March 10, 2023

By Federal Court Electronic Filing System

Federal Court of Canada
701 West Georgia Street
Vancouver, BC V7Y 1B6

Attn: Judicial Administrator

Dear Sir/Madam:

Re: Safe Food Matters Inc. v Attorney General of Canada and others
Court File No. T-2292-22

We are counsel for the Applicant, Safe Food Matters Inc., in the above-noted matter. We write pursuant to the Order of Associate Judge Horne made February 10, 2023. We ask that this letter brought to the attention of Associate Judge Benoit Duchesne at your earliest convenience.

Status Update

The Applicant received leave to file an Amended Notice of Application on January 20, 2023.

On January 30, 2023, the Respondent identified irrelevant and privileged passages in certain documents in the Certified Rule 317 Record that were inadvertently not redacted prior to delivery and filing. The Applicant has agreed to delete the documents in respect of which the Respondent claims privilege, and the Respondent has agreed that that the passages it identified as irrelevant need not be redacted.

On February 1, 2023, the Applicant requested that the Respondent supplement the Certified Rule 317 Record to include documents dealing with the newly amended issues. The Respondent has not responded to this request. The Applicant intends to bring application to require the Respondent to supplement the Certified Rule 317 Record.

The Applicant has been advised that a group of environmental non-governmental organizations may wish to apply for intervener status.

Proposed Timetable for Next Steps

The Applicant proposes the following timetable for next steps:

a) The Respondent respond to the Applicant's request for supplemental documents on or before March 24, 2023;

b) The Respondent file any supplemental Certified Rule 317 Record on or before April 6, 2023;

c) The Applicant serve and file any application to require the Respondent to supplement the Certified Rule 317 Record on or before April 21, 2023;

d) Any application to intervene be served and filed on or before April 21, 2023;

e) The balance of the schedule, including deadlines for filing affidavits, expert reports, cross-examination and exchange of written arguments, may be set by agreement of the parties.

Availability for Case Management Teleconference

The Applicant is available for a Case Management Teleconference on March 16, 17, and 20-24, 2023. The Applicant has requested the Respondent's availability but has not received a response to that request.

Thank you for your attention.

Respectfully yours,

*Jason Gratl**

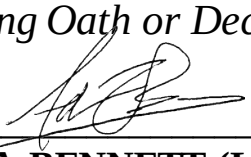
JG/jk

Copy: Counsel for the Attorney General of Canada (by electronic mail)

511-55 EAST CORDOVA STREET • VANCOUVER, BC • V6A OA5
PHONE: 604-694-1919 • FAX: 604-608-1919
www.gratlandcompany.com *A Law Corporation

THIS IS **EXHIBIT "J"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Department of Justice Canada
Ministère de la Justice Canada

Ontario Regional Office
National Litigation Sector
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Toronto Ontario M5H 1T1
Canada

Région de l'Ontario
Secteur national du contentieux
120, rue Adelaide ouest, pièce 400
Toronto (Ontario) M5H 1T1

Telephone/Téléphone: (647) 256-7510
Email/Courriel: kathryn.hucal@justice.gc.ca

March 14, 2023

Our File Number: LEX-500112902

VIA ONLINE FILING

The Registrar
Federal Court of Canada
180 Queen Street West
2nd Floor
Toronto, ON M5V 3L6

Dear Registrar:

Re: Safe Food Matters Inc. v. Attorney General of Canada and Minister of Health
Court File No. T-2292-22

I am writing further to the letter from Mr. Gratl dated March 10, 2023 in which he confirms that the Applicant will delete documents in the CTR over which Canada claims privilege. I had been awaiting his response on that issue at which time I said I would be in a position to indicate my availability for a case conference. I can advise the Court I am available for a case conference March 20 -24.

In addition, I can also advise the Court that the Respondent does not intend to provide any supplemental documents nor to file a supplemental CTR. The Respondent consents to the balance of the suggested timetable.

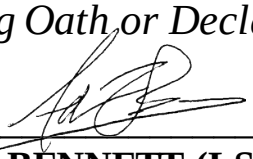
Sincerely,

Kathryn Hucal
General Counsel
KH:ea

c. Jason Gratl, Gratl & Company Barristers and Solicitors, Counsel for the Applicant
(Via email: jason@gratlandcompany.com)

THIS IS **EXHIBIT "K"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Federal Court Cour fédérale

Date: 20230321

Docket: T-2292-22

Ottawa, Ontario, March 21, 2023

PRESENT: Case Management Judge Benoit M. Duchesne

BETWEEN:

SAFE FOOD MATTERS INC.

Applicant

and

ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

ORDER

UPON reading the letters filed by the parties on March 10 and March 14, 2023, setting out a proposed timetable for the next steps in this proceeding;

AND UPON HEARING from the solicitors for the parties during a case management conference held on March 14, 2023;

AND CONSIDERING that it is appropriate to make an Order pursuant to Rule 385(1)(a) and (b) of the *Federal Courts Rules*, SOR/98-106 (the "*Rules"*);

THIS COURT ORDERS that:

1. The Tribunal and the Respondents shall, by March 24, 2023, pursuant to Rule 318(2) of the *Rules*, inform all of the parties and the Court in writing of the reasons for its objection or refusal to transmit a supplementary certified tribunal record as requested by the Applicant pursuant to Rule 317 of the *Rules* of its Notice of Application.

2. If the Applicant elects to have the tribunal and the Respondents' objection to transmit a supplementary certified tribunal record determined, then:

    a) the Applicant shall serve its affidavits in support of its position by April 21, 2023;

    b) the Respondents shall serve their affidavits in support of their position by May 19, 2023;

    c) the Applicant shall serve and file its Motion Record, including its affidavits and memorandum of fact and law, with proof of service thereof, by May 29, 2023;

    d) the Respondents shall serve and file their Responding Record, including their affidavits and memorandum of fact and law, with proof of service thereof, by June 8, 2023; and,

    e) the hearing of the challenge to the objection will be heard remotely on June 13, 2023, commencing at 9:30 P.S.T. (12:30 E.S.T) for a full day.

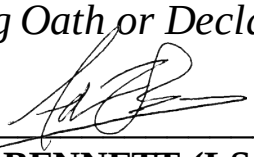
3. Any person or party seeking to intervene in this proceeding may serve and file their Motion Record for leave to intervene pursuant to Rule 109 of the *Rules* by

April 21, 2023, and either party may serve and file any Responding Record in accordance with the *Rules*.

"Benoit M. Duchesne"
Case Management Judge

THIS IS **EXHIBIT "L"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

GRATL & COMPANY

BARRISTERS AND SOLICITORS

March 22, 2023

By Electronic Mail (kathryn.hucal@justice.gc.ca)

Department of Justice Canada
400-120 Adelade Street West
Toronto, Ontario
M5H 1T1

Attn: Kathryn Hucal

Dear Sir/Madam:

Re: Safe Food Matters Inc. v Attorney General of Canada and others
Court File No. T-2292-22

We are counsel for the Applicant, Safe Food Matters Inc., in the above-noted matter.

I write to formalize the record for the purpose of my client's application to require the respondent to supplement the Certified Tribunal Record. I appreciate that you have not taken any issue with service or formality but I thought it appropriate to reiterate the nature of our request for documents.

My client formally requests that the respondent supplement the Rule 317 Certified Tribunal Record with the following documents:

1) There are no records of the communications or documents generated by the so-called "Tiger Team" that were assigned to deal with the PMRA's interpretation of its enabling statute. I would expect numerous emails and draft briefing notes and memoranda. The members of the "Tiger Team" are not legal counsel. The interpretation of PMRA's enabling statue is at the core of this judicial review;

2) There are no records dealing with PMRA's interpretation of the significance of the "Monsanto Papers", although the materials disclosed show that PMRA communicated internally about these papers and generated analyses of these papers. These papers are important because they address the need for transparency and independence, and the public perception thereof, in respect of the role of the PMRA and the need for an independent review panel to ensure transparency, accountability and the public perception thereof. The PMRA's ability and willingness to address the distortions of science (ie. ghostwriting, data manipulation, undisclosed conflicts of interest) evidenced in those documents and the non-independent

relationships between Monsanto and glyphosate-related lobby and research groups disclosed by those documents is relevant to this judicial review.

3) The redactions of the glyphosate reports under Volume 1, Tab 40 and Tab 42, appear on their face to be overbroad. The names of report authors, among other things, appear to be redacted. The claimed basis for the redactions of Tab 40 is "confidential data". The claimed basis for the redactions of Tab 42 is "confidential". I ask that counsel conduct a review of these redactions. I know of no legal basis for redacting the names of the authors of the studies.

4) Documents dealing with PMRA's review of 5 studies in Dr. Portier's letter to EFSA are not included in the materials. I would expect that PMRA has a copy of Dr. Portier's letter to EFSA, internal communications dealing with these five studies and Dr. Portier's letter, and the EPA and EFSA reviews of the studies. Vol.1, tab 45 sets out a powerpoint presentation apparently given by Kimberly Low which implies the existence of many documents dealing with Dr. Portier's letter. I refer you to documents at Vol.1, p.1504, and p.1509 of the record at page 8.

5) Documents dealing with PMRA contact with Monsanto representatives, including Croplife, dealing with glyphosate. The lobby registry refers to many contacts between Croplife (Monsanto's agent) and Manon Bombardier (ADM, PMRA Transformation), Peter Brander (PMRA Executive Director), Frederic Bissonette (PMRA Chief Registrar), Richard Aucoin (PMRA Executive Director), and others within PRMA. Any communications between PMRA and Croplife and/or Monsanto employees or lobbyists that deal with glyphosate should form part of the record.

Thank you for your attention.

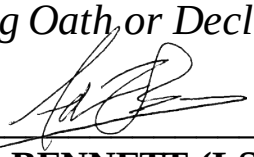
Respectfully yours,

*Jason Gratl**

JG/jk

THIS IS **EXHIBIT "M"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Department of Justice Canada | **Ministère de la Justice Canada**

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Telephone/Téléphone: (647) 256-1659
Email/Courriel: walter.kravchuk@justice.gc.ca

March 24, 2023

Our File Number: LEX-500112902

VIA E-MAIL [jason@gratlandcompany.com]

Mr. Jason Gratl
Gratl & Company
Barristers and Solicitors
511-55 Cordova St. E
Vancouver, BC
V6A 0A5

Dear Mr. Gratl:

Re: Safe Food Matters Inc. v. Attorney General of Canada and Minister of Health
Court File No. T-2292-22

Further to the March 20, 2023 CMC before the Case Management Judge Duchesne, and in response to your letter dated March 22, 2023, please be advised that the basis for the R.318(2) objection is as follows.

The additional materials requested in items #2, 4 and 5 of your letter are irrelevant to the decision of the *Pest Management Regulatory Agency* ("PMRA") which is the subject of this judicial review application.

With respect to the request in item #1 of your letter, we are reconsidering the position, scope, and basis of our client's objection. Regarding item #3, our client will provide the names of the studies' authors.

We will endeavour to provide complete answers for items #1 and 3 by the end of next week.

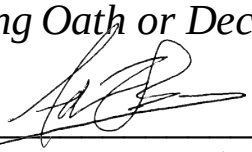
Sincerely,

Walter Kravchuk
Counsel, National Litigation Sector
WK: ea

Canada

THIS IS **EXHIBIT "N"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Department of Justice Canada | **Ministère de la Justice Canada**

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Telephone/Téléphone: 647-256-1659
Fax /Télécopieur: 416-973-0809
Email/Courriel: Walter.Kravchuk@justice.gc.ca

Our File Number: LEX-500112902

EMAIL (Nicole.Hradsky@cas-satj.gc.ca**)**

March 27, 2023

Federal Court
180 Queen Street West, Suite 200
Toronto, ON, M5V 3L6

Attention: Nikki Hradsky

Dear Madam:

Re: Informal Request Letter
Safe Food Matters Inc. v. Attorney General of Canada and Minister of Health
T-2292-22

On or about December 15, 2022, a Certified Tribunal Record ("CTR"), parts 1 and 2 was transmitted to the Court. However, it has come to our attention that an un-redacted version of part 2 was inadvertently transmitted to Jason Gratl, Applicant's counsel, and the Court.

Upon realizing this error, we wrote to Mr. Gratl seeking that he and others from his office to destroy all copies of the un-redacted part 2 of the CTR. On March 10, 2023, our office received a letter from Mr. Gratl where he indicated he would delete the privileged portions of part 2. We are now in a position to re-transmit part 2 of the CTR on consent of all parties.

The "amended" CTR, part 2 with applied redactions regarding the solicitor-client privileged content has been uploaded onto the Court's SharePoint site. Should you have any questions, please do not hesitate to contact our office.

Sincerely,

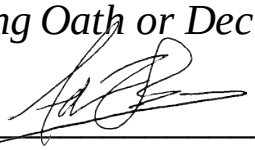
Walter Kravchuk
Counsel
National Litigation Sector

c. Jason B. Gratl, solicitor for the Applicant (via email)

Canada

THIS IS **EXHIBIT "O"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Federal Court  Cour fédérale

OTT, ON

April 11, 2023

BY E-MAIL

Counsel for the Applicant
Jason Gratl
jason@gratlandcompany.com

Counsel for the Respondent
Kathryn Hucal
kathryn.hucal@justice.gc.ca

Dear parties:

RE: SAFE FOOD MATTERS INC. v. AGC ET AL
Court File No.: T-2292-22

This is to advise of the following Direction of the Associate judge Duchesne dated April 11th, 2023:

"I hereby direct pursuant to Rule 72(2)(a) that the tribunal's amended CTR Part 2 can be accepted by the Court. Please note that the CTR is not "filed" by any party unless part of an Application Record, Responding Record or other Record, but is transmitted to the and received by the Registry pursuant to Rule 318."

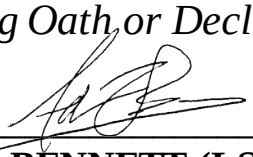
Yours truly,

Mariana Rilko Alvarenga

Mariana Rilko Alvarenga
Registry Officer

THIS IS **EXHIBIT "P"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

From: Hucal, Kathryn
Sent: April 11, 2023 3:54 PM
To: 'jason@gratlandcompany.com'; Kravchuk, Walter; jodi@gratlandcompany.com
Cc: Zita-Bennett, Adrian; Aydoner, Ezel (she; her | elle; la); 'Toby Rauch-Davis'
Subject: RE: Safe Food Matters Inc. v AGC et al. (Court file no. T-2292-22)

Hello Jason,

These privilege claims were made in the earlier judicial review application which resulted in the decision currently before the court in this judicial review. Previous counsel did not challenge these claims. Therefore it is our position that this matter has been finally concluded.

Kathryn

Kathryn Hucal
General Counsel | Avocate-générale
National Litigation Sector / Secteur national du contentieux
Department of Justice Canada/Ministere de la Justice Canada
Ontario Regional Office/Bureau regional de l'Ontario
120 Adelaide Street West
Suite #400
Toronto, Ontario M5H 1T1
Tel | Tél: 647 256-7510
Fax | Téléc 416 952-0298

From: jason@gratlandcompany.com <jason@gratlandcompany.com>
Sent: Thursday, March 30, 2023 1:15 PM
To: Kravchuk, Walter <Walter.Kravchuk@justice.gc.ca>; jodi@gratlandcompany.com
Cc: Hucal, Kathryn <Kathryn.Hucal@justice.gc.ca>; Zita-Bennett, Adrian <Adrian.Zita-Bennett@justice.gc.ca>; Aydoner, Ezel (she; her | elle; la) <Ezel.Aydoner@justice.gc.ca>; 'Toby Rauch-Davis' <toby@gratlandcompany.com>
Subject: RE: Safe Food Matters Inc. v AGC et al. (Court file no. T-2292-22)

Hi Walter,

The Respondents reliance on Confidential Business Information and Confidential Test Data privilege are freshly made, today.

I write to request pursuant to Rule 317(2) that you identify the entity or entities on whose behalf and/or in reference to which you claim Confidential Business Information (CBI) and Confidential Test Data (CTD). I further request production of the confidentiality agreements that underly those claims.

Please confirm that you accept service of this email.

Best regards,

Jason

From: Kravchuk, Walter <Walter.Kravchuk@justice.gc.ca>
Sent: Thursday, March 30, 2023 9:37 AM
To: jason@gratlandcompany.com; jodi@gratlandcompany.com
Cc: Hucal, Kathryn <Kathryn.Hucal@justice.gc.ca>; Zita-Bennett, Adrian <Adrian.Zita-Bennett@justice.gc.ca>; Aydoner, Ezel (she; her | elle; la) <Ezel.Aydoner@justice.gc.ca>
Subject: Safe Food Matters Inc. v AGC et al. (Court file no. T-2292-22)

Mr. Gratl,
This will respond to items #1 and #3 of your letter dated March 22, 2023.

#1 The Respondent objects to this request on the grounds of irrelevance and privilege. Nonetheless, we are continuing to review these communications and documents. We will advise if our client's position changes.

#3 We enclose Tabs 40 and 42 without the authors' names redacted. Please note that other redactions are maintained on the basis of Confidential Business Information (CBI) and Confidential Test Data (CTD).

Regards,

Walter

Walter Kravchuk
Counsel / Avocat
National Litigation Sector / Secteur National du Contentieux
Ontario Regional Office / Bureau Régional de l'Ontario
Department of Justice Canada / Ministère de la Justice Canada
120 Adelaide St. West, Suite 400 / 120, rue Adelaide Ouest, Pièce 400
Toronto, ON, M5H 1T1

Tel : 647.256.1659
E-mail : walter.kravchuk@justice.gc.ca

Canada

From: Aydoner, Ezel (she; her | elle; la) <Ezel.Aydoner@justice.gc.ca>
Sent: Friday, March 24, 2023 3:21 PM
To: 'jason@gratlandcompany.com' <jason@gratlandcompany.com>
Cc: 'jodi@gratlandcompany.com' <jodi@gratlandcompany.com>; Hucal, Kathryn <Kathryn.Hucal@justice.gc.ca>; Kravchuk, Walter <Walter.Kravchuk@justice.gc.ca>; Zita-Bennett, Adrian <Adrian.Zita-Bennett@justice.gc.ca>
Subject: Safe Food Matters Inc. v AGC et al. (Court file no. T-2292-22)

Good afternoon Mr. Gratl,

Please find attached, correspondence addressed to you from Walter Kravchuk.

Kindly,

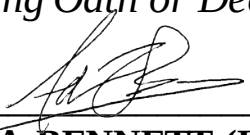
Ezel Aydoner (she/elle)
Legal Assistant to Walter Kravchuk | Adjointe Juridique de Walter Kravchuk

Litigation Extradition Advisory Division | la Division du contentieux, de l'extradition et du service consultatif
Department of Justice Canada | Ministère de la Justice Canada
Ontario Regional Office | Bureau régional de l'Ontario
120 Adelaide Street West/ 120 rue Adelaide Ouest
Suite 400/ Pièce 400
Toronto, Ontario, M5H 1T1
Ezel.Aydoner@justice.gc.ca

Canada

THIS IS **EXHIBIT "Q"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Department of Justice Canada
Ministère de la Justice Canada

Ontario Regional Office
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120 Adelaide Street West Suite #400
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Région de l'Ontario
Secteur national du contentieux
120, rue Adelaide ouest, pièce 400
Toronto, ON M5H 1T1

Telephone/Téléphone: 416-526-2299
Fax/Télécopieur: 416-973-0809
Email/Courriel: Adrian.Zita-Bennett@justice.gc.ca

April 14, 2023

VIA EMAIL (Nicole.Hradsky@cas-satj.gc.ca; TOR_reception@fct-cf.ca)

Registry
Federal Court of Canada
180 Queen Street West, Suite 200
Toronto, ON M5V 3L6

Dear Madam:

Re: Informal Request Letter
Safe Food Matters Inc v Attorney General of Canada and Minister of Health
Court File No.: T-2292-22

Further to our letter of March 27, 2023, the Respondents received a request from Mr. Gratl, Applicant's counsel, on March 22, 2023, requesting further documentation with respect to the Certified Tribunal Record ("CTR"). For your reference, enclosed is a copy of Mr. Gratl's request.

A review of the documentation in light of Mr. Gratl's objection resulted in compilation of volume of the CTR, part 3, which was transmitted to Mr. Gratl on April 14, 2023.

The Respondents would appreciate the Court's assistance in receiving access to the Court's SharePoint site in order to transmit CTR, part 3.

Thank you for your consideration of this letter.

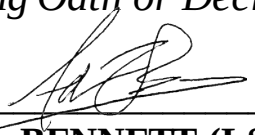
Adrian Zita-Bennett
Counsel
National Litigation Sector

Enclosed

cc: Jason Gratl, Gratl & Company, jason@gratlandcompany.com
Counsel for the Applicant

THIS IS **EXHIBIT "R"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Federal Court Cour fédérale

OTT, ON

May 8, 2023

BY E-MAIL

Counsel for the Applicant
Jason Gratl
jason@gratlandcompany.com

Counsel for the Respondent
Kathryn Hucal
kathryn.hucal@justice.gc.ca

Counsel for the Proposed Intervener
Bill Jeffery
Litigation@HealthScienceAndLaw.ca

Dear parties:

RE: SAFE FOOD MATTERS INC. v. AGC ET AL
Court File No.: T-2292-22

This is to advise of the following Direction of the Associate Judge Duchesne dated May 8, 2023:

> *"I hereby direct pursuant to Rule 72(2)(a) of the Federal Court Rules that the tribunal's CTR Part 3 can be accepted by the Court as being transmitted to the Court and kept in the appropriate annex to the Court file."*

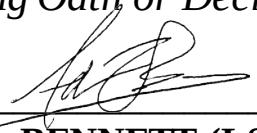
Yours truly,

Mariana Rilko Alvarenga

Mariana Rilko Alvarenga
Registry Officer

THIS IS **EXHIBIT "S"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

From: jodi@gratlandcompany.com
Sent: April 21, 2023 4:04 PM
To: Hucal, Kathryn; Kravchuk, Walter
Cc: jason@gratlandcompany.com; Zita-Bennett, Adrian; Mozaffar, Hilda
Subject: Safe Food Matters Inc. v AGC et al. / Fed Court File No.: T-2292-22

Good Afternoon,

Pursuant to the Order of Case Management Judge Benoit M. Duchesne of March 21, 2023, we enclose the following affidavits for service:

1) Affidavit #1 of Mary Lou McDonald, affirmed April 21, 2023;
2) Affidavit #2 of Jodi Kaldestad, affirmed April 19, 2023;
3) Affidavit #3 of Jodi Kaldestad, affirmed April 2023; and
4) Affidavit of Jason MacLean, affirmed April 20, 2023.

Due to the volume of the affidavits, we are unable to send them by email directly, so they have been uploaded to the Dropbox link below:

https://www.dropbox.com/scl/fo/jwzxudq6646nyqouszwt2/h?dl=0&rlkey=sl06vr6tna6lnmxeqrmqtyjho

Kindly advise if you accept electronic service of these documents.

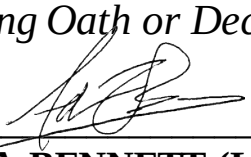
Kind Regards,

Jodi Kaldestad
Paralegal

Gratl & Company
Barristers and Solicitors
511-55 East Cordova Street
Vancouver, BC V6A 0A5
604-694-1919 (t)
604-608-1919 (f)
www.gratlandcompany.com

THIS IS **EXHIBIT "T"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

From:	Genevieve Rondeau
Sent:	April 21, 2023 3:30 PM
To:	Hucal, Kathryn; Zita-Bennett, Adrian; Kravchuk, Walter; jason@gratlandcompany.com
Cc:	Sean Montague; Randy Christensen
Subject:	T-2292-22 - SAFE FOOD MATTERS INC. v. AGC ET AL - Motion Record of the Proposed Interveners Environmental Defence Canada Inc. & Friends of the Earth Canada
Attachments:	T-2292-22 Motion Record of the Proposed Interveners, April 21, 2023.pdf

Good afternoon,

Please find attached, a copy of the Motion Record of the Proposed Interveners in the subject captioned court file, which is duly served on you today. The complete list of counsel for the Respondents has been updated to reflect my conversation with Mr. Walter Kravchuk this afternoon.

Should you experience any difficulties accessing this file, please contact the undersigned for options to resolve the issue.

Please acknowledge service at your earliest convenience.

Best regards,

Genevieve Rondeau (she/her)
Legal Administrative Assistant/Office Administrator | Ecojustice
520-1801 Hollis Street, Halifax, NS B3J 3N4
K'jipuktuk Mi'kma'ki
T: 902-417-1700 | 1-800-926-7744 ext. 641
F: 902-417-1701

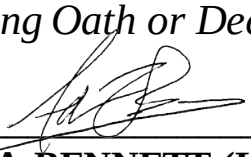
I am grateful to live and work in the traditional, ancestral and unceded territory of Mi'kma'ki (MEEG-MA-GEE), the traditional (or ancestral) territory of the Mi'kmaq people. I endeavour to keep the promise and continue living in peace and friendship together on these lands we share.

ecojustice

Ecojustice is Canada's largest environmental law charity. Help us build the case for a better earth.

THIS IS **EXHIBIT "U"** mentioned and referred to in the Affidavit of Ezel Aydoner.

AFFIRMED remotely by Ezel Aydoner in the City of Guelph, in the province of Ontario, before me at the City of Toronto, in the province of Ontario, on this 18th day of May 2023, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*.



ADRIAN ZITA-BENNETT (LSO# 84848K)
A COMMISSIONER FOR TAKING AFFIDAVITS

Prepared May 18, 2023

Notice of Objection JR - Registry of Lobbyists Chart

Environmental groups	Links
Center for Health Science & Law	https://lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=357894&regId=917122
Eco-Justice Canada	https://lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=222662&regId=931998
Environmental Defence Canada	https://lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=13022&regId=931577
Équiterre	https://lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=269143&regId=930445
David Suzuki Foundation / Fondation David Suzuki	https://lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=16500&regId=932277

TAB 2

Court File Number: T-277-19

FEDERAL COURT

MARY LOU MCDONALD and
SAFE FOOD MATTERS INC.

(Applicants)

and

ATTORNEY GENERAL OF CANADA

(Respondent)

Service of a copy hereof admitted
this 12 day of February
2019
Solicitor for Attorney General of Canada

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

NOTICE OF APPLICATION

TO THE RESPONDENT(S):

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

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 (place where Federal Court of Appeal (or Federal Court) ordinarily sits).

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 applicant's solicitor, or where the applicant is self-represented, on the applicant, 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.

February 11, 2019

ORIGINAL SIGNED BY
KEVIN LEMIEUX
A SIGNÉ L'ORIGINAL

Issued by: _____
(Registry Officer)

I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on / and dated:

FEV FEB 11 2019

KEVIN LEMIEUX / REGISTRY OFFICER

Address of local office:
Canadian Occidental Tower
635 Eighth Avenue S.W. 3rd Floor
P.O. Box 14
Calgary, Alberta
T2P 3M3

TO:
Attorney General of Canada
c/o Deputy Attorney General of Canada
Office of the Deputy Attorney General of Canada
284 Wellington Street
Ottawa, Ontario
K1A0H8

AND TO:
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, Ontario
Address locator
K1A 0K9
pmra.infoserv@hc-sc.gc.ca

APPLICATION

This is an application for judicial review in respect of the decision of the Minister of Health and the Pest Management Regulatory Agency ("PMRA") not to establish a panel of one or more individuals under Section 35(3) of the *Pest Control Products Act establish (the "Act")* to review the decision to register glyphosate upon completion of a re-evaluation, as outlined in a letter of the PMRA dated January 11, 2019 (the "Decision"), which establishment was requested under the Notice of Objection ("NOO") filed by Mary Lou McDonald, in her personal capacity, and also filed by Safe Food Matters Inc. (collectively, the "Applicants"), under Section 35(1) of the Act.

The Applicants make application for:

1. An order quashing the Decision;
2. An order directing the Minister to establish a panel of one or more individuals to review the decision to register glyphosate (the "Registration Decision"), or, in the alternative, remitting the Decision to the Minister for reconsideration in accordance with any direction or guidance of the Court;
3. Costs of this application; and
4. Such other relief a counsel may advise and the Court deems just.

The grounds for the application are:

1. On April 13, 2015, the PMRA issued Proposed Re-evaluation Decision PRVD2015-01 in which it proposed the continued use of registration of products containing glyphosate for sale and use in Canada. It stated that "[a]n evaluation of available scientific information found that products containing glyphosate do not present unacceptable risks to human health or the environment when used according to the proposed label directions".

2. On April 28, 2017, the PMRA issued Re-evaluation Decision RVD2017-01 ("RVD 2017-01") in which it granted continued registration of products containing glyphosate for sale and use in Canada. It stated that "[a]n evaluation of available scientific information found that products containing glyphosate do not present risks of concern to human health or the environment when used according to the revised label directions. As a requirement for the continued registration of glyphosate uses, new risk reduction measure are required for the end-use products registered in Canada. No additional data are being requested at this time.

3. On June 27, 2017, the Applicants submitted the Notice of Objection to PMRA. Mary Lou McDonald submitted the NOO as someone is directly affected by RVD 2017-01 because she relies on the consumption of lentils and chickpeas to maintain good health and glyphosate is found in high levels in these crops, and Safe Food Matters Inc. ("SFM") is a non-profit corporation whose stated purpose is to promote public health and protect the environment.

4. The NOO set out 9 objections (each, an "Objection") to RVD 2017-01 and provided support based on science and reason, including references to studies, literature, government publications and policy documents. The NOO indicated:

> *The main basis for this objection is that glyphosate applied for desiccation purposes is placing residues in the seeds to that extent that they exceed MRLs and are of concern to human health, especially considering increased consumption of the relevant foods, and that* ***evidence of such translocation and accumulation has not been considered*** *in the Re-evaluation or contemplated in the law. The support for this is set out in point 1-4 below. The remaining points provide other objections.*
>
> *1) Desiccation with Glyphosate on Crops Causes MRL Exceedances*
> *2) Evidence of Dietary Exposure to Glyphosate as a Desiccant Not Examined in PRVD2015-01*
> *3) Evidence that Dietary Exposure of Desiccated Crops has Increased*
> *4) MRLs for Unregistered Products Have Not Been Set as Required by the Act*
> *5) Label Amendments Don't Address the Risk*
> *6) No Consideration of Whether Labels are Followed*
> *7) Enforcement of Any Imposed Label Requirements on Desiccants Not Likely*
> *8) Unlikely that Following Labels Will Bring No Harm, since Statutory Regime Contemplates Exceedances of MRLs Even When Labels are Followed*
> *9) Reductions of Safety Factor Without Scientific Rationale*

5. On January 11, 2019 at noon EST the PMRA issued the Decision to the Applicants and all other objectors, and then held a technical briefing with objectors at 2 pm EST ("Technical Briefing").

6. In the Technical Briefing, PMRA representatives read the "Statement from Health Canada on Glyphosate" (the "Statement"), and the Statement was posted on the Health Canada website on January 11, 2019. The Statement indicated that "Health Canada scientists reviewed the information provided in these notices [of objection], **and assessed the validity of any studies in question**, to determine whether any of the issues raised would influence the result of the assessment and associated regulatory decisions".

7. Also in the Technical Briefing, a representative indicated that very small levels of glyphosate in food are not unexpected, and that one of the reasons for establishing Maximum Residue Levels ("MRLs") is to help ensure safety of the food supply. She indicated that MRL exceedances do not automatically indicate a health risk.

8. Sections 2 and 4 of the Act provide as follows:

> **Acceptable risks**
> **(2)** For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **Primary objective**
> **4 (1)** In the administration of this Act, the Minister's primary objective is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

9. Section 35 of the Act provides as follows:

> **35** (1) Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.
>
> (2) Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision to authorize the export of a pest control product or to amend or cancel an authorization within 60 days after a notice referred to in subsection 33(6) or 34(4) is made public.
>
> (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.
>
> (4) The Minister shall give public notice of the establishment of a review panel.
>
> (5) If the Minister does not establish a panel, the Minister shall provide written reasons without delay to the person who filed the notice of objection.
>
> (6) The Minister may determine the terms of reference of a review panel and the procedure for the review, and may at any time change them.
>
> (7) A review panel shall give any person a reasonable opportunity to make representations in respect of the decision under review, in accordance with the terms of reference.
>
> (8) Subject to subsections 44(3) and (6), the hearings of a review panel shall be open to the public.

10. The Review Panel Regulations (the "Regulations") apply to the establishment of the panel to review the Registration Decision. Section 3 of the Regulations provides as follows:

> 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.

11. Section 7 of the Act requires that the Minister apply a scientifically based approach in evaluating the health and environmental risks of a product, and the Minister shall also look at "available information" on exposure, namely dietary exposure:

> Scientific approach
>
> (7) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall
>
> (a) apply a scientifically based approach; and
>
> (b) in relation to health risks, if a decision referred to in paragraph 28(1)(a) or (b) is being made or has been made in relation to a pest control product,
>
> (i) among other relevant factors, consider available information on aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational source...

12. The Health Canada *Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* (August 1, 2000) (the "Decision Making Framework") provides (at 8):

> Make Effective Use of Sound Science Advice
>
> Success in maintaining and improving our health requires an evidence based approach to decision making. This can only be achieved by making effective use of sound science advice. Such an approach helps to address public confidence that decision makers are using science in the best interests of Canadians, that science advice is credible, and that decision makers are confident that this advice is based on a rigorous and objective assessment of all available information. In

order to achieve these goals, the decision making process must include measures to ensure the quality, integrity and objectivity of science advice (Council of Science and Technology Advisors, 1999, Industry Canada, 2000).

13. The Decision did not consider or reasonably consider the factors set out in s.3 of the Regulations. It did not examine whether information in the NOO raised scientifically founded doubt as to the validity of the evaluation of glyphosate in RVD2017-01. The Decision did not apply or reasonably apply a scientifically based approach or examine the relevant factors as required by s.7 of the *Act*.

14. The Decision was comprised of a cover letter and then Attachment 1. In the cover letter, the PMRA made the following statements:

    a. "The purposes of notice of objection is to identify the area of science supporting the re-evaluation decisions to which objection is taken, to provide the scientific basis of the objection and to request that the area of science in question be referred to a review panel for reconsideration and recommendation" (the "PMRA Stated Purposes").

    b. "The notice of objection, including the scientific rationale, was assessed by a team of PMRA evaluators who were not involved in the original re-evaluation decision. This team provided recommendations as to the requirement for a review panel based on the validity and the scientific plausibility of the issues raised in the notice".

    c. "The factors to be considered in determining whether to establish a review panel include (1) whether the information in the notice raises scientifically founded doubt as to the validity of the evaluations.... of the health and environmental risks of the pesticide; and (2) whether the advice of a review panel of expert scientists would assist in addressing the subject matter of the objection."

15. The Decision indicated that the information provided in the NOO did not meet either of the two factors and accordingly does not provide the basis for establishing a review panel.

16. In Appendix 1, the PMRA characterized the Objections as "Comments", and provided written responses to only six of the nine Objections made by the Applicant. It did not provide responses to Objections 6, 7 or 8. The Minister failed to take into account the proposed conditions of the labels for glyphosate, as required by the Act. The Minister failed to consider whether Objections 6, 7 and/or 8, which deal with the sufficiency of the PMRA's labelling regime, raise any scientific doubt about the validity of the evaluation. The Minister failed to consider the label directions and thereby failed to consider whether 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 when it is used according to the label directions. The Minister

failed to consider whether the advice of a review panel of expert scientists would assist in addressing the subject matter of the objection. In failing to consider the information provided in the NOO dealing with the efficacy or lack of efficacy of glyphosate labels, label compliance and labelling enforcement in determining whether the risks to human health, future generations and the environment are acceptable, the Minister failed to take a scientific approach to assessing the validity of the evaluation.

17. With respect to Objection 1, that *Desiccation with Glyphosate on Crops Causes MRL Exceedances*:

    a. The Applicants pointed to scientific literature that showed two things: that the earlier glyphosate is applied as a desiccant, or the more moisture content there is in the plant when it is applied, the higher the residue levels in the plant (the "Translocation Point"). It then indicated that these higher levels have resulted in exceedance of the legally prescribed maximum residue limits ("MRLs") for some crops (the "MRL Exceedance Point"). This MRL Exceedance Point has been shown in Canada with data obtained from the Canada Food Inspection Agency ("CFIA"), that showed violations in 36.6% of the chickpea samples. The MRLs used by CFIA were "Canadian MRLs, United States tolerances or Codex MRLs, which was greater". The Applicants cited PRVD2015-01 stating that a pesticide residue that does not exceed established MRLs does not pose a health risk concern, and posited that "foods that DO exceed the established MRLs DO pose a health risk".

    b. The PMRA Response to Objection 1 was that the scientific literature show that residues increase when the moisture content is more than 30%, that the labels of registered glyphosate products indicate that the application must be conducted at less than 30% moisture content, and the residue data used to establish MRLs were based on this use pattern. It indicated that glyphosate residues on food have been measured in field trial studies that are required to register a pesticide for specific uses. It also indicated that an exceedance of an MRL does not automatically equate to a potential health risk of concern, and that "when pesticide residue levels exceed the MRL, follow-up action for non-compliant products, taken by the Canadian Food Inspection Agency (CFIA), are initiated in a manner that reflects the magnitude of the health concern."

18. The Minister's approach to the MRL Exceedances Point is not in compliance with the Regulations, which require only that a "scientifically founded doubt" be raised. The Minister's approach to non-compliant products of condoning "follow-up actions" that 'reflect the magnitude of the health concern" differs from the statutory requirement that the exceedences raise "some doubt about the validity of the evaluations". Because the Minister's response to Objection 1 also assumes the efficacy of the labels for glyphosate products, label compliance and label enforcement, the

Minister's failure to respond to Objections 6, 7 and 8 is rendered even more unreasonable.

19. With respect to Objection 2, that *Evidence of Dietary Exposure to Glyphosate as a Desiccant Not Examined in PRVD2015-01*:

    a. The Applicants indicated that there is no discussion of dietary exposure to glyphosate through harvest management or desiccation in PRVD 2015-01. They state it appears 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, and that such an examination is necessary given the mechanisms already described by which MRLs can be exceeded in desiccated crops, and that CFIA data shows exceedances are occurring in fact.

    b. The PMRA Response to Objection 2 was that the dietary risk assessment conducted in the re-evaluation encompasses all registered food uses, including desiccated crops, and it pointed to Appendix V "Supervised residues trial studies", which "supported a maximum seasonal rate of ...0.9 kg ae/ha in preharvest applications for .... all other crops".

20. The Minister's response to Objection 2 is unreasonable and unscientific and fails to take into account relevant factors and ignores the evidence. Objection 2 deals with dietary exposure arising from increasing concentrations of glyphosate in the seed sinks of certain plants by the mechanism of translocation, which occurs when plants that are already growing and have a certain moisture content are desiccated. The Minister's response to Objection 2 speaks to the rate of application, not the timing or the moisture content of the plant, and thereby does not address relevant issues and fails to comply with the statutory and regulatory requirements.

21. With respect to Objection 3, that *Evidence that Dietary Exposure of Desiccated Crops has Increased:*

    a. The Applicants referenced SPN2003-3 to describe how exposure to a pesticide is determined, and indicate that the consumption data that is used for dietary exposure risk assessments is inadequate because it is from the mid1990s. They provided statistical and other evidence that consumption of chickpeas has increased significantly since the mid-1990s, and pointed to Statistics Canada statistics that show that total domestic use of pulse and special crops increased from 2010-11 to 2016-7 by 250%. They indicated that the increase in consumption of pulses and special crops, particularly those subject to desiccation by glyphosate, is evidence and data that is required for an accurate current assessment of glyphosate.

    b. The PMRA Response to Objection 3 was that it relies upon the "Dietary Exposure Evaluation Model – Food Commodity Intake Database™ (DEEM-

FCID™ Version 2.14) program, which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. It indicated that even with more recent versions of DEEM, "dietary exposure is not expected to be of concern".

22. The Minister's response to Objection 3 speaks ignores the evidence and fails to take into account information that is accurate and current, which is information needed for a valid evaluation. The Minister does not consider or take into account relevant factors and fails to comply with the statutory and regulatory requirements. PRMAs Response did not even comment on the increased consumption but just pointed to DEEM. This is despite the fact that the August 2018 document of Health Canada *The Use of Dietary Intake Data in Dietary Exposure Assessments within Health Canada: Current Practices, Challenges and Perspectives* set out 2 key limitations in conducting dietary exposure assessment within Health Canada (at 15, 16), namely:

"There is no existing national database on food consumption that meets the specific requirements for conducting evaluation/ assessment across all HC organizations" and

"Several barriers exist to accessing the necessary information, tools and capacity for an effective selection and integration of dietary intake data in exposure assessments".

23. With respect to Objection 4, *MRLs for Unregistered Products Have Not Been Set as Required by the Act*:

a. The Applicants set out Sections 9, 10 and 11 of the Act, and indicate that Subsection 9(3) [sic: should be 10(3)] essentially requires the Minister to evaluate only the health risks of a product when specifying MRLs for unregistered products or uses. The use of glyphosate as a desiccant on chickpeas is an unregistered use. The Applicants state: (1) there is no indication that the use of desiccation on non-conventional crops of chickpeas, lupin, faba bean, canary seed, camelina, mustard and forage crops (the "Additional Crops") was looked at; or (2) that MRLs have been set for desiccation use of these Additional Crops.

b. The PMRA Response to Objection 4 was to reference the URMULE submissions it looked at to review the health risks from glyphosate residues as a result of preharvest use on the Additional Crops, and to indicate desiccant use on these crops does not pose health risks. The URMULE submission reviewed for chickpeas was described as (Sub. No. 2015-1580).

Submission No. 2015-1580 provided by PRMA did not, however, examine residues. It provided, under the section "Health Assessment" that: "A food residue assessment for glyphosate in/on chickpeas was not required since glyphosate is currently registered for uses on dry beans (including chickpeas).

24. The PMRA in its Response to Objection 4 misapplied the law to the facts. Section 7 of the Act requires a consideration of available information on dietary exposure in evaluating whether the health risks of glyphosate are acceptable, and the examination did not occur, contrary to what the PMRA indicates.

25. With respect to Objection 9, *Reductions of Safety Factor Without Scientific Rationale*:

    a. The Applicants state the Act requires the application of a margin of safety, if glyphosate is used in or around homes or schools, that is 10 times great than the margin of safety that would otherwise be applicable, unless the Minister determines "on the basis of reliable scientific data" that a different margin of safety would be appropriate. The Applicants claim that the PMRA lowered the safety factor in at least two instances without reliable scientific rationale.

    b. The PMRA Response was that "the PMRA believes, however, that the co-occurrence of high-end food, drinking water and residential exposure scenarios will often be impossible or, at best, highly unlikely".

26. The Minister's belief in the likelihood or co-occurrence exposure scenarios has no basis in reliable scientific data. In the response to Objection 9, the Minister applies a different test than the statutory requirement that there be reliable scientific data to lower the margin of safety. The Minister jettisons the standard widespread margin of safety the Act requires be used without a scientific basis for doing so.

27. This administrative process was also incorrect and unreasonable. By submitting the issue of whether the NOO raises a doubt about the validity of the evaluation to a non-expert team of PMRA evaluators, the Minister and the PMRA circumvented and acted inconsistently with ss.35(7) and (8) of the *Act*, which provide participants with an opportunity to make submissions to the expert panel and provide that the expert panel's hearings be open to the public. Section 4 (b) of the Review Panel Regulations requires that the evaluators on a review panel not have been employed in any department, in any division or branch of the federal public administration, in any corporation or in any parent Crown corporation ... within one year before the day on which they are appointed, which evidences the intent of the legislation that there be no apparent conflict of interest. In contrast, the evaluators process followed by the Minister was not free from an apparent conflict of interest, and it was neither open to the public nor afforded participants with an opportunity to make representations to the expert panel. The Minister acted beyond its jurisdiction, improperly delegated its duties under the Act and circumvented legislative intention by using an opaque, non-participatory and non-expert process.

28. The Decision was incorrect, or in the alternative, unreasonable in that:

    a. it applied the wrong legal test in rejecting the NOO. The test is not whether the studies relied on are valid, which is what was forwarded by PMRA in the

Statement. The test is not as set out in the PMRA Stated Purposes. The correct test is whether a scientific doubt is raised about the validity of the evaluations. A valid evaluation must be based on science that complies with the requirements of the Decision Making Framework. A valid evaluation is a rigorous and objective assessment of all available information, and the decision making process must include measures to ensure the quality, integrity and objectivity of science advice. An evaluation is not valid it if relies upon old scientific studies and dietary information and does not include an evaluation of new information;

b. it failed to take the proper factors into account when rejecting the NOO;

c. It misinterpreted the Act when it justified the reduction of the safety factor;

d. It was based on an erroneous finding of fact that food residues had been examined; and

e. It was made without regard to the material before the PMRA.

29. The Minister of Health and the PMRA acted contrary to law.

30. The Minister of Health and the PMRA failed to take into account statutory requirements for the establishment of a review panel.

This application will be supported by the following material:

- A supporting affidavit to be sworn, with exhibits, including:
  1. The June 27,2017 Notice of Objection of the Applicants;
  2. The January 11, 2019 Decision of PMRA;
  3. The email record of correspondence with SFM and Mary Lou McDonald;
  4. The Pest Control Products Act;
  5. The Review Panel Regulations;
  6. Regulatory Directive 98-02;
  7. Submission No. 2015-1980;
  8. The January 11, 2019 Statement from Health Canada on Glyphosate;
  9. Transcript from the Technical Briefing;
  10. The Use of Dietary Intake Data in Dietary Exposure Assessments within Health Canada: Current Practices, Challenges and Perspectives;
  11. The SPN-2001 Science Policy Notice: Technical Paper: A Decision Framework for Risk Assessment and Risk Management states;
  12. Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks (August 1, 2000); and

- Such other evidence as counsel may advise, and this Court deems just.

The Applicants request the Minister of Health and the PMRA to send a certified copy of the following material that is not in the possession of the Applicants but is in the possession of the Minister of Health or the Pest Management Regulatory Agency to the Applicants and to the Registry:

- The complete record before the Minister of Health and the PMRA in the Proposed Re-evaluation Decision PRVD2015-01, in the Re-evaluation Decision RVD2017-01, and the review of the Notice of Objection of the Applicants;

February 11, 2019

Mary Lou McDonald in her personal capacity and as solicitor for Safe Food Matters Inc.
9 Boardwalk Drive Unit 107 Toronto ON M4L 6T1
905 467-8531 safefoodmatters@gmail.com

Transmission Log

Justice Canada Thursday, 2019-02-14 15:02 7804958491

Date	Time	Type	Job #	Length	Speed	Station Name/Number	Pgs	Status
2019-02-14	15:01	SCAN	13302	0:23	31200	403 292 5329	1	OK -- V.34 1M31

Court File Number: T-277-19

FEDERAL COURT

MARY LOU MCDONALD and SAFE FOOD MATTERS INC.

(Applicants)

and

ATTORNEY GENERAL OF CANADA

(Respondent)

Service of a copy hereof admitted this 12 day of February 2019

Solicitor for Attorney General of Canada

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

NOTICE OF APPLICATION

TO THE RESPONDENT(S):

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

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 (place where Federal Court of Appeal (or Federal Court) ordinarily sits).

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 applicant's solicitor, or where the applicant is self-represented, on the applicant, 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.

Court File No.

FEDERAL COURT

BETWEEN:

MARY LOU MCDONALD and
SAFE FOOD MATTERS INC.

Applicants

- and -

ATTORNEY GENERAL OF CANADA

Respondent

NOTICE OF APPLICATION

Mary Lou McDonald, LL.B.
Mary Lou McDonald Professional Corporation
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905 467-8531

Lawyers for the Applicants

137

Federal Court Cour fédérale

Facsimile Transmittal Form / Formulaire d'acheminement par télécopieur

TO / DESTINATAIRE(S):

Name / Nom: DOJ – Civil Litigation

Katherine Chandler-Pillipow

Facsimile / Télécopieur: (780) 495-8491

FROM / EXPÉDITEUR: CALGARY REGISTRY	DATE: Feb 11 2019
Telephone / Téléphone: (403) 292-5920	TIME / HEURE: 2:17
Facsimile / Télécopieur: (403) 292-5329	Total Number of pages (including this page) / Nombre de pages (incluant cette page): 15

SUBJECT / OBJET: T-277-19

COMMENTS / REMARQUES:

Documents for service pursuant to Rule 133.

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Thank you.

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TAB 3

Court File No. T-2292-22

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

AMENDED 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: Issued by: _____
(Registry Officer)

Address of local office:
Federal Court
200-180 Queen Street West
Toronto, Ontario M5V 3L6

TO: ATTORNEY GENERAL OF CANADA
c/o DEPARTMENT OF JUSTICE CANADA
Ontario Regional Office
3400 – 130 King St W, Box 36
Toronto, ON M5X 1K6

TO: MINSITER OF HEALTH
70 Colombine Driveway,
Tunney's Pasture
Postal Location: 0906C
Ottawa, ON K1A 0K9
Phone: (613) 957-0200
Fax: (613) 952-1154
c/o DEPARTMENT OF JUSTICE CANADA
Ontario Regional Office
3400 – 130 King St W, Box 36
Toronto, ON M5X 1K6

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. In September of 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 <u>scientifically reliable information</u> 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, including the central requirement to address "[t]he 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";

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. The PMRA fails to consider the meaning and purpose of s.35 of the *Act* or the *Regulations* and the significance of an option created specifically and expressly to access a source of scientific review and recommendations that is independent of PMRA, on which more is said below.

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. It 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 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 unreasonable, inconsistent with the purpose and intent of the *Act* and *Regulations*, and 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 Discussion 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 and capacity for answering the tests rests exclusively 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. The New Decision does not articulate the logical or practical relationship between these purported criteria, on one hand, and the purpose and intent of s.35 of the *Act* and the statutory function of a review panel as it relates to PMRA and the Minister, on the other hand.

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 unduly 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.

The Review Panel: A Reliable, Structured, Statute-based Source of Independent Review and Recommendation for the Minister to Assist in Discharging his/her Statutory Function

94. The Applicant submits that, reasonably interpreted, s.35 of the *Act* and the *Regulations* provide the Minister with a structured discretion to appoint a review panel, with a review panel consisting of a source of independent review and recommendation of health risk and product benefit as structured by terms of reference, and subject to a specific requirement that the panel may consist only of qualified scientific experts without conflicts of interest who have not been employed within the civil service for at least a year. Upon receipt of a NoO, it is mandatory for the Minister to consider the factors under s.3 of the *Regulations* in deciding whether to appoint a review panel.

95. The Minister is required to consider two factors under s.3 of the *Regulations*, but has discretion to consider other factors not listed in s.3. The Applicant says that the only reasonable interpretation is that the *Act* and *Regulations* require that Minister must establish a review panel when the Minister concludes, after consideration of the two factors set out in s.3 of the *Regulations*, that a review panel is necessary to fulfil his or her statutory mandate. If both of the factors set out in s.3 of the *Regulations* are satisfied, then the Minister should conclude, unless sufficient countervailing considerations are found to exist, that a review panel is necessary.

96. The Applicant submits that in addition to the purpose and intent of the *Act*, the Court should have regard to the meaning of the legislated words "in their entire context", in accordance with *Rizzo & Rizzo Shoes*. This includes regard to Hansard and other aspects of legislative context, including facts about the PMRA as an institution and its capacities and infirmities as set out in official reports and publications, and context dealing with the nature of the regulated entity in relation to the regulator.

Interpretive Analysis

97. Interpreting these statutory provisions, as the FCA rightly directed, requires interpretating "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 Applicant says that within the context and purpose of the *Act*, a review panel exists only to make recommendations to the Minister, to assist the Minister in deciding under s.35 of the *Act* whether to confirm, reverse or vary the decision. Recommendations by independent expert scientists would assist the Minister only when the independent review panel can offer the Minister something that the civil service (including those employed within the PMRA) cannot or does not provide.

98. The provision under s.3 of the *Regulations* requiring the Minister to consider looking outside the civil service for advice and recommendations is unusual because it expressly recognizes that the civil service may be unable to provide the scientific advice or analysis the Minister requires to fulfil his or her statutory duties. However, s.3 of the *Regulations* is consistent with the preamble the *Act* requiring recourse to "diverse sources" of information. Section 35 of the *Act* and the *Regulations* reflect Parliament's intention to ensure that the Minister does not unreflectively rely exclusively on the civil service in deciding whether to confirm, reverse or vary a registration, re-evaluation or special review decision of the PMRA.

99. The Applicant says that it is implicit in the structure of s.35 of the *Act* and the *Regulations* that the Minister's powers under s.35 **not** be delegated to internal PMRA

staff. Although the Minister is ordinarily entitled to delegate the exercise of his or her powers to others, the situation changes in respect of a NoO filed under s.35, which triggers a requirement that the Minister assess whether the Minister would benefit from independent advice from qualified experts outside the civil service (ie. non-PMRA scientists).

100. Parliament cannot reasonably be taken to have authorized PMRA to assess the utility of sources of information outside itself. Delegation of s.35 powers to PMRA staff violates the precept that a decision-maker should not be the judge in its own cause: *nemo iudex in cause sui*. Moreover, delegation of the decision whether to appoint a review panel to PMRA is inconsistent with the pillar requiring public confidence in decision-making. It would be absurd for PMRA,shortly after making a registration decision, to decide whether it is desirable or necessary for PMRA to look outside PMRA for help in reconsidering its own decision. In this case, the New Decision was improperly made by the Chief Registrar of the PMRA, rather than the Minister.

101. PMRA appears to be well aware of the tension inherent in being the judge in its own cause as it asserts, presumably in an attempt to alleviate the tension, that different PMRA scientists were involved in the decision to appoint a review panel decision than were involved in the original approval decision. However, this attempt is unreasonable and inadequate. It does not enhance public confidence in a review decision when PMRA staff are unwilling to be critical of the capacities of their office-mates and colleagues, of the validity of their decisions.

102. The Minister's statutory power of appointing a review panel when necessary under s.35 of the *Act* and s.3 of the *Regulations* should be distinguished from the usual test for administrative bias. The criteria for appointing a review panel are not as restrictive or constrained as the test for a finding of administrative bias. In applying s.35 of the *Act*, the Minister is not constrained by a presumption of PMRA's capacity and the evidence of potential benefit from a qualified review panel need not be as concrete. No finding that PMRA cannot decide fairly or is in a conflict of interest is necessary under s.35 of the *Act*. Rather, the Minister must engage in an

inquiry as to whether independent advice would be of assistance to the Minister in fulfilling his or her statutory mandate by helping to identify, analyze and weigh risks to public health and/or assess the value of the pest control product.

103. The Minister must be attentive to and consider the presence of factors that are suggestive to an informed member of the public that the Minister's ability to fulfil the statutory function would be enhanced by receiving recommendations from an independent panel. These might include:

- A regulated entity that maintains significant control or influence over the evidence or information used by PMRA to render the decision to be reviewed;
- A relative lack of diversity of informational sources;
- A regulated entity or sector that has a long-term relationship with PMRA leading up to the decision to be reviewed;
- The presence of staff secondments or transition of staff between PMRA and the regulated entity or its agents;
- Any influence of the regulated entity on PMRA funding or finances;
- Relative scientific expertise as between PMRA and the regulated entity or sector;
- Imbalance of resources as between PMRA and the regulated entity or sector;
- Past or present substantive irregularities in decisions involving the regulated entity (such as bypassing or failing to apply long-standing risk thresholds or safeguards);
- Past or present procedural irregularities in decisions involving the regulated entity (such as administrative delay or lack of transparency or public consultation in decision-making);

- Administrative or institutional capacity limitations or concerns currently identified or under consideration.

104. In determining whether scientific advice independent of PMRA would assist in fulfilling his or her statutory mandate, the Minister must have regard to considerations involving bureaucratic infirmity, lethargy, incapacity or inadequacy of any type on the part of the PRMA, including consideration of regulatory capture. In this context, this assessment would involve looking at the relationship between Monsanto (including its agents) and PMRA, and whether a reasonable person might have a basis to believe, in the whole of the context, that the advice of independent expert scientists of the type set out in s.4 of the *Regulations* would "assist" the Minister.

105. In considering these factors, the Minister should be concerned not only with the integrity or validity of the decision, but with the appearance of integrity and validity of the decision to members of the public, in light of the potential magnitude of the harm. The greater the risk to the public, the greater the necessity for an independent scientific review panel. Here, Monsanto's Roundup glyphosate products are the most widely used herbicides in Canada, and glyphosate is a known toxin and carcinogen. The magnitude of the risk of widespread dispersal of unsafe levels of glyphosate is on the higher end of the scale of importance that the Minister discharge his or her statutory functions on the basis of a scientifically valid evaluation.

106. Section 4 of the *Regulations* requires a review panel to be composed of persons who have been free from federal government employment for at least a year and who are free of any conflicts of interest. Being a civil servant or recently having been a civil servant is a disqualification, and reflects Parliament's acknowledgement that government employees may lack capacity for independence of the relevant type. Although this may be an uncomfortable reality for the civil service, Parliament has concluded that being a civil servant working within an institutional setting may in some ways make it more difficult to provide an appropriate, adequate or fulsome scientific evaluation for the purposes of making recommendations to the Minister.

107. In contrast with the range of considerations the Applicant submits should be considered by the Minister, the New Decision confines the PMRA to an unreasonably narrow list of considerations or criteria which could suggest that a review panel would assist the Minister:

- The fact that PMRA staff concur with one another;
- The fact that PMRA concurs with other government regulators;
- The fact that different PMRA staff had addressed the Notice of Objection;
- The fact that the science is not novel.

108. The narrow approach taken by the PMRA in the New Decision is unreasonable in the sense that the PMRA has failed to grasp the literal meaning contextual implications of ss.3 and 4 of the *Review Panel Regulations* and has failed to articulate a practical or logical link between criteria and the statutory and regulatory framework.

109. In particular, the factors listed by the PMRA are irrational and unreasonable in the sense that internal PMRA consensus and concurrence with foreign regulators are at best neutral factors. As might be expected when an institution like PMRA judges its own cause, the PMRA proves itself unable to fathom or grasp the possibility that its own evaluation, upon which its decision is based, might not be valid and that the Minister may benefit from the recommendations of qualified scientists outside PMRA. Here, where Parliament has effectively legislated that PMRA's institutional self-criticism may well be prone to failure and its self-awareness may be incomplete, PMRA's "internal consensus" model is an unreasonable approach.

110. The decision under review provides a good example: PMRA appears to have achieved "internal consensus" on an evaluative approach that is manifestly invalid (e.g. using decades-outdated dietary consumption data). In this case, PMRA's internal consensus on a clear methodological error is a positive indication that a

review panel is necessary with respect to s.3 of the *Regulations*. PMRA's new consensus, in response to the NoO, that using updated chickpea consumption modelling data yields only unimportant exceedances of Maximum Residue Limits, further proves the point: internal consensus within PMRA cannot rationally or reasonably be treated as proof that independent scientific advice from a review panel is unnecessary. The absence of any dissenting scientists within PMRA who would defend the decades-long commitment of PMRA to MRLs as a human health threshold does not enhance confidence in PMRA's response to the NoO.

111. The Minister can take no comfort in PMRA's statement that all the scientists within PMRA later agreed that it was an error for all the scientists within PMRA to initially agree to evaluate glyphosate using outdated consumption modelling data. The whipsaw lurching from one perfect internal consensus to another is alarming; the absence of dissenting voices within PMRA in negating the significance of MRL exceedances may well be an indication that something has gone methodologically astray within PMRA.

112. PMRA's conformity with the evaluation of foreign regulators is also an unreasonable standard for negating a review panel. PMRA, like other Canadian regulators (CSA, Health Canada, Environment Canada, etc.), is often perceived to follow or copy the United States Environmental Protection Agency without engaging in thorough independent evaluation. One example of this tendency is the PMRA's unreflective use of (outdated) US dietary consumption data to perform its initial evaluation. Conformity with a foreign regulator is a virtue only if the evaluation conducted by the foreign regulator is valid within the Canadian statutory framework. Adoption of conformity with foreign regulators as a legal standard for contraindicating a review panel is unreasonable and irrational in the entirety of the context.

113. The Applicant submits that to perform his or her statutory function under ss.3 and 4 of the *Regulations*, the Minister should consider structural features within PMRA and adjudicative patterns within PMRA that would tend to diminish or erode public confidence that the Minister's statutory obligations have been satisfactorily

discharged. Here, PMRA failed to consider the institutional capacity issues within PMRA that are presently being addressed, including a lack of scientific capacity, failures of public transparency, lack of internal conflict of interest controls, and other organizational issues that currently impede PMRA's fulfilment of its mandate.

114. Section 35 of the *Act* and s.4 of the *Regulations* lessen the presumption of executive impartiality and the presumption of regularity and direct the Minister to engage in reflection on whether independent scientific recommendations would improve the protection of the public and improve regulatory approaches to specific products and regulated entities. In this exercise, PMRA is not entitled as an institution to unreflective deference.

115. Here, the PMRA have done the opposite of what is required. In responding to the Notice of Objection, PMRA failed to analyze the significance of a dramatic increases in hummus (ie. glyphosate) consumption, downplayed exceedances of long-standing Maximum Residue Limit health risk thresholds and introduced new analytic distinctions between direct and indirect desiccation. Internal consensus within PMRA with these controversial divergences from established PMRA policies and practices are a sign that advice from experts outside the PMRA is necessary to assist the Minister, rather than a sign that a review panel is unnecessary.

116. Importantly, PMRA failed entirely to remark on the significance of the fact that its staff scientists had failed to detect that they had used human food consumption data that was dramatically out of date, failed to identify the exceedances, and had failed to incorporate the (supposed) distinction between direct and indirect desiccation into their initial analysis. PMRA's failure to consider the significance of its methodological failures demonstrates that the Minister (not PMRA) should exercise the powers under s.35 of the *Act*.. Furthermore, PMRA's failure to consider the problems with its own decision demonstrate the need for an independent review panel. The primary focus, when determining whether to establish a review panel, is on whether the initial decision is valid and based on complete information and analysis, not on whether a re-evaluation by PMRA can mend its infirmities.

When is a Review Panel Required?

117. The Applicant says there is only one reasonable interpretation of s.35 of the *Act* and ss.3 and 4 of the *Regulations*: the Minister must establish a review panel when the Minister concludes, after consideration of the factors set out in s.3 of the *Regulations*, that a review panel is necessary to fulfil his or her statutory mandate. If both of the factors set out in s.3 of the *Regulations* are satisfied, then the Minister should conclude, unless sufficient countervailing considerations are found to exist, that a review panel is necessary. It is unreasonable to suppose that Parliament intended government employees within PMRA to exercise power under s.35 of the *Act*.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

118. ~~94~~ An affidavit from a representative of the Applicant, to be served;

119. ~~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

120. ~~96~~ Such further and additional materials as counsel may advise and the Court may allow.

Rule 317 Request

121. ~~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.

Jason Gratl

Date: December 20, 2022.
~~October 31, 2022.~~

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TAB 4

Court File No.: T-2292-22

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.

Applicant

- and -

ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

MEMORANDUM OF FACT AND LAW OF THE RESPONDENTS

June 8, 2023

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Counsel for the Respondents, Attorney General of Canada and Minister of Health

OVERVIEW

1. The Applicant's motion under Rule 317 and Rule 318 should be dismissed. The decision maker in this case – the Minister's delegate, the Pest Management Review Agency ("**PMRA**") – has complied with its relevant obligations under Rule 318[1] by transmitting the records that were before the decision maker when the decision under review was made.

2. The purpose of Rule 317 of the *Federal Courts Rules* (the "**Rules**") is to ensure that the record that was before the relevant decision maker is placed before the court and/or that a proper objection is made where the record cannot be transmitted. This ensures that a reviewing court can properly discharge its role in reviewing the reasonableness of administrative decisions.

3. The jurisprudence emphasizes that the Rule is not to be used as a vehicle to conduct a fishing expedition, nor to seek documentary production, as in an action. Yet, this is exactly what the Applicant seeks to do. The Applicant seeks documents beyond what the PMRA considered when making the decision under review; and documents unrelated to the grounds for review and grounds upon which the Applicant originally based its notice of objection. They include, among other things, the "Monsanto papers" as well as communications between PMRA and Croplife.

PART I - STATEMENT OF FACTS

4. The underlying judicial review application is of a redetermination decision of the PMRA pursuant to the judgment of the Federal Court of Appeal ("**FCA**") dated February 2, 2022.[2] In that decision, the FCA set aside the Federal Court's judgment dated February 13, 2020, quashed the PMRA's decision dated January 11, 2019, and remitted the matter back to the PMRA for redetermination in accordance with the reasons.

5. In its reasons, the FCA suggested that the PMRA should communicate how it had regard to the following:

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[1] *Federal Courts Rules*, SOR/98-106, r. 318 ["***Federal Courts Rules***"]
[2] *Safe Food Matters Inc v. Canada (Attorney General)*, 2022 FCA 19 ["***SFM Appeal***"]

a) The specific text, context and purpose of the preamble of the *Pest Control Products Act* ("***Act***");

b) The definitions of "health risk" and "acceptable risks" in subsections 2(1) and 2(2) of the *Act*;

c) Consideration of the primary objective of the Act set out in subsection 4(1) of the *Act*;

d) 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*;

e) 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*;

f) 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*;

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

h) 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*.[3]

6. The FCA further suggested that the PMRA should then explain why it had made the decision it had, based on its interpretation of the legislation and its factual findings.[4]

7. In offering this guidance, the FCA made it clear it was not proposing any particular outcome on the merits of the matters before the PMRA.[5]

Background

8. PMRA, acting on behalf of the Minister of Health, is responsible for the federal regulation of pesticides in Canada in accordance with the *Act* and regulations thereunder.[6]

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[3] *SFM Appeal*, para.65
[4] *SFM Appeal*, para.66
[5] *SFM Appeal*, para.67
[6] *Pest Control Products Act*, SC 2002, c 28 [the "***Act***"]; *Pest Control Products Regulations* (SOR/2006-124) ["***PCP Regulations***"]; *Review Panel Regulations* (SOR/2008-22) ["***Panel Regulations***"]; *Interpretation Act* (R.S.C., 1985, c. I-21), s. 24 ["***Interpretation Act***"]; *Carltona Ltd. v. Commissioners of Works* [1943] 2 All E.R. 560 (C.A.)

A) Legislative Framework

9. The purpose of the *Act* is to protect human health and safety and the environment by regulating products used for the control of pests. The Minister's primary objective in administering the PCPA is to prevent unacceptable risks to individuals and the environment from the use of pesticides. This is accomplished through what the FCA described as three pillars consisting of: 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 to enhance decision making and increase public confidence in it."[7]

10. 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**").[8]

11. Section 16 of the *Act* requires PMRA to 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.[9] 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.[10]

12. During a re-evaluation, PMRA uses a science-based approach in conducting its risk assessment.[11] 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.[12]

13. 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.[13] 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.[14]

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[7] *SFM Appeal*, para. 1
[8] *Act*, s. 9 and s. 11(1)
[9] *Act*, s. 16(2)
[10] *Act*, s. 16(1)
[11] *Act*, s. 19(2)(a)
[12] *Act*, s. 28
[13] *Act*, s. 21(1)
[14] *Act*, s. 21(2)

PMRA publishes its final re-evaluation decision.

14. Any person may file with the Minister a Notice of Objection ("**NOO**") to a final re-evaluation decision within 60 days after the final decision is published.[15] 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.[16] 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.

15. 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,

b. whether the advice of expert scientists would assist in addressing the subject matter of the objection.[17]

16. 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.[18]

B) Regulation of Glyphosate

17. In 1976, glyphosate was registered for use in Canada and has been continuously registered for use since then. In 2005, the PMRA gave approval to a label expansion that allowed glyphosate to be used as a pre-harvest desiccant on a variety of crops, including chickpeas. In 2009, the PMRA gave notice of its intention to re-evaluate glyphosate to determine whether it should remain registered for use. On April 13, 2015, the PMRA made public a proposed re-evaluation decision. In response to the proposed re-evaluation decision, the Applicant provided written comments and

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[15] *Act*, s. 35
[16] *Panel Regulations*, s. 2(c) and (d)
[17] *Panel Regulations*, s. 3
[18] *Act*, s. 35(5)

participated in the public consultation process.[19]

18. In 2017, after completing the public consultation process, the PMRA published a final re-evaluation decision permitting the continued registration of glyphosate products for use in Canada, which decision summarized the public comments received, as well as PMRA's responses to those comments.[20]

19. The release of the PMRA's re-evaluation decision triggered another right under the *Act*. Sixty days after a re-evaluation decision is released, subsection 35(1) of the *Act* allows any person to object to it with reasons with a NOO.[21]

Applicant's Notice of Objection (NOO) 2017-3047

20. The Applicant filed an objection, submission number (2017-3047), in accordance with s.35 of the *Act*. The main allegation for objection being "that glyphosate applied for desiccation purposes is placing residues in the seeds to the extent that they exceed MRLs and are of concern to human health, especially considering increased consumption of the relevant foods and that evidence of such translocation and accumulation has not been considered in the Re-evaluation or contemplated in the law." In addition, there were concerns about labelling and reductions of safety factor. These concerns were enumerated as nine objections to the Final Re-evaluation Decision.[22]

21. In the NOO, the Applicant did not make reference to the "Monsanto papers" or Dr. Portier's Letter, and did not raise any related objections or concerns.

22. On January 11, 2019, in written reasons, the PMRA considered the objections raised in the Applicant's NOO and exercised its discretion not to establish a review panel (the "**2019 Decision**").[23]

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[19] *SFM Appeal*, para. 4
[20] CTR, Volume 2 at page 2254
[21] *SFM Appeal* paras. 5-6
[22] *Applicant's Record*, pages 546-561
[23] *SFM Appeal*, para. 9 ; *Applicant's Record*, pages 599-606

Judicial Review

23. The Applicant's application for judicial review dated February 11, 2019 challenged the lawfulness of the 2019 Decision. It was dismissed on the basis that the Applicant failed to raise an issue of scientific doubt concerning the validity of PMRA's evaluations such that the PMRA's decision not to appoint a review panel to assist it in addressing any issue of scientific doubt was not unreasonable.[24] The grounds listed in the Notice of Application[25] included:

a. That the decision was incorrect or unreasonable in that it applied the wrong legal test in rejecting the NOO;

b. That the decision failed to take proper factors into account when rejecting the NOO;

c. That the PMRA misinterpreted the *Act* when it justified the reduction of the safety factor;

d. That the decision was based on an erroneous finding of fact that food residues had been examined;

e. That the decision was made without regard to the material before the PMRA;

f. That the Minister of Health and the PMRA acted contrary to law; and

g. That the Minister of Health and the PMRA failed to take into account statutory requirements for the establishment of a review panel.

24. The Applicant did not raise any objections or concerns regarding the objectivity, bias or regulatory capture of the PMRA, or raise any objections or concerns in respect of the Monsanto Papers or Dr. Portier's Letter as part of the First Judicial Review.

Appeal

25. The Applicant successfully appealed this decision. The FCA in its reasons determined that: i) the PMRA's decision failed to provide legislative interpretation of relevant statutory and

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[24] *McDonald v. Canada (Attorney General)*, 2020 FC 242 ["***First Judicial Review***"], paras. 19 and 74

[25] Notice of Application (T277-19), dated February 11, 2019, at Tab 2 of the Motion Record of the Respondents

regulatory provisions;[26] and ii) the Court was unable to discern the legislative interpretation from the record.[27] The FCA issued guidance to the PMRA when interpreting its legislation, noting that the Court "was not proposing any particular outcome on the merits of the matters before the PMRA".[28]

Redetermination Decision

26. By letter dated September 29, 2022, the Applicant was provided a 33-page decision outlining the PMRA's interpretation of legislation and regulations regarding the objections raised by the Applicant. In that decision, the Applicant was provided a detailed explanation in response to every objection raised in the NOO.[29]

27. In accordance with the direction from the FCA, PMRA interpreted scientifically-founded doubt and set out when external experts would be beneficial through the criteria it developed and applied as part of the redetermination.

28. Ultimately, it was concluded that (a) the information provided in the NOO did not raise scientifically-founded doubt as to the validity of the evaluations, on which the decision (RVD2017-01) was based regarding the health risk assessment for glyphosate; and (b) that the advice of expert scientists would not assist in addressing the subject matter of the objection. As such, it was not necessary to establish a review panel to consider any of the objections raised in the NOO.[30]

29. An application for Judicial Review of this decision dated October 31, 2022 was filed with the Court.[31] It was amended on December 20, 2022[32] by the current counsel, and consists of 121 paragraphs and is 38 pages in length.[33]

30. In its Amended Notice of Application, ("**ANOA**"), the Applicant challenges the

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[26] *SFM Appeal*, paras. 44-57
[27] *SFM Appeal*, paras. 58-62
[28] *SFM Appeal*, paras. 65 and 67
[29] Redetermination Decision, dated September 29, 2022, CTR, Vol. 2, pages 147-179
[30] *Ibid.*
[31] Affidavit of Ezel Aydoner, affirmed May 18, 2023 ["***Aydoner Affidavit***"], para. 4
[32] *Aydoner Affidavit*, para. 6
[33] Amended Notice of Application, at Tab 3 of the Motion Record of the Respondents

redetermination decision on four grounds, stating that the new decision is unreasonable and procedurally unfair for the following reasons

a. the PMRA did not have regard to at least three of the Guidance points directed by the FCA and still fails to interpret the legislation, including the central requirement to address the specific role and purpose of a review panel, versus the role and purpose of the PMRA, when it receives a NOO;
b. the PMRA fails to apply its interpretation of the legislation and does not comply with the legislative constraints;
c. the PMRA's criteria guiding application of s.3 of the Regulation are not justified, intelligible, or rational and do not comply with applicable legislative constraints; and
d. the introduction of the Review Panel Criteria is procedurally unfair.[34]

The Applicant's Rule 317 Requests

31. In its ANOA, the Applicant requested:

a. All documents in the possession of the Minister, or the PMRA, 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; and
    iii. All PMRA policies, guidance or practices relied on in the New Decision.[35]

32. The Certified Tribunal Record, ("**CTR**") Volumes 1 and 2 were transmitted to the Federal Court and the parties on December 15, 2022. Volume 1 consists of documents initially reviewed by the PMRA when making its 2019 decision that was sent back for redetermination by the FCA, by order dated February 2, 2022. CTR Volume 2 contains the additional relevant documents that were before the PMRA on redetermination.

[34] ANOA dated December 20, 2022, pages 13-37
[35] ANOA dated December 20, 2022, pages 37-38

33. By letter dated March 22, 2023, Applicant's counsel made the following request, seeking that additional documents be included in the CTR ("**CTR Request**"):

1) There are no records of the communications or documents generated by the so called "Tiger Team" that were assigned to deal with the PMRA's interpretation of its enabling statute. I would expect numerous emails and draft briefing notes and memoranda. The members of the "Tiger Team" are not legal counsel. The interpretation of PMRA's enabling statute is at the core of this judicial review;

   The Respondents satisfied this request in the form of CTR, Volume 3 by way of letter dated April 14, 2023[36].

2) There are no records dealing with PMRA's interpretation of the significance of the "Monsanto Papers", although the materials disclosed show that PMRA communicated internally about these papers and generated analyses of these papers. These papers are important because they address the need for transparency and independence, and the public perception thereof, in respect of the role of the PMRA and the need for an independent review panel to ensure transparency, accountability and the public perception thereof. The PMRA's ability and willingness to address the distortions of science (ie. ghostwriting, data manipulation, undisclosed conflicts of interest) evidenced in those documents and the non-independent relationships between Monsanto and glyphosate-related lobby and research groups disclosed by those documents is relevant to this judicial review.

3) The redactions of the glyphosate reports under Volume 1, Tab 40 and Tab 42, appear on their face to be overbroad. The names of report authors, among other things, appear to be redacted. The claimed basis for the redactions of Tab 40 is "confidential data". The claimed basis for the redactions of Tab 42 is "confidential". I ask that counsel conduct a review of these redactions. I know of no legal basis for redacting the names of the authors of the studies.

   The Respondents satisfied this request by way of letter dated March 30, 2023, providing the names of the authors. [37]

4) Documents dealing with PMRA's review of 5 studies in Dr. Portier's letter to EFSA are not included in the materials. I would expect that PMRA has a copy of Dr. Portier's letter to EFSA, internal communications dealing with these five studies and Dr. Portier's letter, and the EPA and EFSA reviews of the studies. Vol.1, tab 45 sets out a Powerpoint presentation apparently given by Kimberly Low which implies the existence of many documents dealing with Dr. Portier's letter. I refer you to documents at Vol.1, p.1504, and p.1509 of the record at page 8.

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[36] *Aydoner Affidavit*, para. 21 and Exhibit "Q"
[37] *Aydoner Affidavit*, Exhibit "P"; *Applicant's Record*, pages 269-433

This request is not addressed in the Applicant's factum and appears to have been abandoned.

5) Documents dealing with PMRA contact with Monsanto representatives, including Croplife, dealing with glyphosate. The lobby registry refers to many contacts between Croplife (Monsanto's agent) and Manon Bombardier (ADM, PMRA Transformation), Peter Brander (PMRA Executive Director), Frederic Bissonette (PMRA Chief Registrar), Richard Aucoin (PMRA Executive Director), and others within PRMA. Any communications between PMRA and Croplife and/or Monsanto employees or lobbyists that deal with glyphosate should form part of the record.[38]

PMRA's Responses to the CTR Request

34. By way of a letter dated March 24, 2023 to the Applicant, the Respondents stated that items 2, 4, and 5 of the CTR Request were irrelevant to the PMRA decision impugned in the ANOA.[39]

35. On or about March 27, 2023, the amended CTR, Volume 2 was transmitted to the Federal Court and the Applicant with applied redactions.[40]

36. Over email exchanges between March 30, 2023 and April 11, 2023, the Respondents clarified their objections to items 1 and 3 of the CTR Request.[41]

37. On April 11, 2023, the Applicant was advised that the redactions on the basis of Confidential Business Information ("**CBI**") and Confidential Test Data ("**CTD**") were maintained, and that these privilege claims were made in the earlier judicial review application, which resulted in the decision currently before the court in this judicial review. The Respondents further stated that previous counsel did not challenge these claims, and this matter has been finally concluded.[42]

38. By way of a letter dated April 14, 2023, the CTR Volume 3 was transmitted to the Federal Court and the Applicant. The documents in Volume 3 pertained to item 1 of the CTR Request.[43]

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[38] *Aydoner Affidavit*, para. 16 and Exhibit "L"
[39] *Aydoner Affidavit*, para. 17 and Exhibit "M"
[40] *Aydoner Affidavit*, para. 18 and Exhibit "N"
[41] *Aydoner Affidavit*, para. 19 and Exhibit "P"
[42] *Aydoner Affidavit*, Exhibit "P"
[43] *Aydoner Affidavit*, para. 21 and Exhibit "Q"

PART II – ISSUE

39. The sole issue in this motion is whether the CTR transmitted by the PMRA complies with Rules 317 and 318.

PART III - SUBMISSIONS

Purpose of Rules 317 and 318

40. Rules 317 and 318 ensure that the record that was before the tribunal whose decision is under review is available for the reviewing court, subject to privilege and public interest immunities. Materials requested under the Rule are restricted to those which were before the decision maker at the time they made the impugned decision and nothing more.[44] The requested materials must be both relevant, and in the possession of the administrative decision maker.[45] Where another entity has supplied information to an administrative decision maker, only the information that was *actually* before the decision maker is obtainable under Rule 317, and not the contents of a file that is not the subject of the judicial review.[46]

41. The relevance of a document is defined by the grounds of review in the notice of application.[47] Frequently, large portions of the tribunal record, particularly in the case of highly specialized agencies, may not be pertinent to the disposition of the issues.[48]

42. The jurisprudence under these Rules has emphasized, time and again, that Rule 317 is not a vehicle for obtaining documentary discovery as in an action. The Courts have been quite clear about this: the Rule 317/318 procedure is not exploratory in nature and its purpose, as noted above, it is to limit discovery of documents to only those that were actually before the decision maker when the decision was made. It does not include all documents that the decision-maker had in its possession.[49]

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[44] *Canadian Constitution Foundation v Canada (Attorney General)*, 2022 FC 1232 at para 14 ["***CCF***"]; *Tsleil-Waututh Nation v. Canada (Attorney General)*, 2017 FCA 128 at para. 112 ["***Tsleil-Waututh Nation***"]

[45] *Tsleil-Waututh Nation* at para. 107; *Canada (Human Rights Commission) v Pathak*, [1995] 2 FC 455; *Democracy Watch v Canada (Attorney General)*, 2021 FC 1417 at para. 15 ["***Democracy Watch***"]

[46] *Tsleil-Waututh Nation at* para. 114

[47] *Tsleil-Waututh Nation* at para. 109

[48] *Athletes 4 Athletes Foundation v. Canada (National Revenue)*, 2020 FCA at paras. 18 and 26

[49] In *Rémillard v. Canada (National Revenue)*, 2020 FC 1061, paras. 55-88, the Court explained the differences between document disclosure under Rules 317/318, and for discovery in an action. ["***Rémillard***"]

43. As the Court in *Rémillard* put it, "[t]he procedure provided for in sections 317 and 318 of the [*Rules*] is simply intended to enable the applicant and therefore the Court to understand the elements on which the decision-maker relied in making its decision."[50] It is not to permit a "fishing expedition" or to look for materials that "could be relevant in the hopes of later establishing relevance." [51]

44. The Applicant's request for production of documents beyond what has already been transmitted goes far beyond the requirements of Rules 317, and cannot be reasonably viewed as anything but a fishing expedition.

Requested Documents Not Relevant

45. The Applicant did not raise any objections in respect of the "Monsanto papers" and Dr. Portier's letter as part of its NOO and, as such, those grounds fall outside the scope of PMRA's decision in relation to the Applicant's NOO.

46. There were eight Notices of Objection filed in 2017 including the Applicant's NOO submission number (2017-3047).[52] While NOOs (2017-2843), (2017-2975), (2017-3015), and (2017-3045) raised concerns regarding the Monsanto Papers, the Applicant's NOO submission (2017-3047) did not.[53] Further, the PMRA's Science Management Committee Briefings show that the Applicant does not reference the Monsanto Papers in its NOO submission.[54] Finally, there is no mention of Dr. Portier in this Applicant's NOO submissions.[55]

47. Documents related to the Monsanto Papers or Dr. Portier' letter were not considered as part of PMRA's decision in relation to this NOO, were not before the decision maker, and are therefore irrelevant to this application for judicial review.

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[50] *Rémillard* at para. 79
[51] *Tsleil-Waututh Nation at* para. 108
[52] CTR, Volume 1 at page 1500
[53] CTR, Volume 1 at pages 315; 1533-1545
[54] CTR, Volume 1 at pages 346-350
[55] CTR, Volume 1 at pages 313-315; 349; 1525-1529; 1543-1544

Allegations of Bias / Regulatory Capture not Raised in the First Judicial Review

48. Materials related to Dr. Portier or the Monsanto Papers were not before the PMRA in the decisions related to this Applicant. Moreover, the Applicant did not request these materials as part of its Rule 317 request in the first judicial review.

49. As this is a redetermination decision and previous counsel did not challenge the contents of the CTR, Volume 1, the time to request these materials has passed, and current counsel is bound by the decisions of his predecessor. In *Raincoast Conservation Foundation v. Canada (Attorney General)*, Justice Stratas relied on well-established doctrines to determine that arguments are barred from being advanced in a later, second proceeding, when they could have been raised in a first proceeding.[56]

50. The Court further stated in *Raincoast Conservation Foundation* referencing *Tsleil-Waututh Nation*:

> …many arguments about the environmental effects of the project either were made or could have been made but were not. Most of the environmental points the applicants now raise are not fairly arguable because they fall into one of these categories. They are barred by the doctrines against relitigation.[57]

51. *Bernard v. Canada (Attorney General)* confirms that specifics of a Court order will dictate the work that must be done on redetermination. An applicant would be precluded from challenging parts of a decision that were not part of the order.[58] The Court also emphasizes that a procedural fairness argument must be raised at the earliest opportunity.[59]

52. An applicant is expected to put their best arguments forward at the first opportunity. To allow the Applicant to now do so is akin to an abuse of process of this Court. As the SCC held in *Behn v. Moulton Contracting Ltd.*, the doctrine of abuse of process is flexible and can apply to prevent an attempt to re-litigate a claim which the Court has already determined, or could have

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[56] *Raincoast Conservation Foundation v. Canada (Attorney General)*, 2019 FCA 224 (CanLII), [2020] 1 FCR 362 at para. 24 ["***Raincoast Conservation Foundation***"]
[57] *Raincoast Conservation Foundation* at para. 38
[58] *Bernard v. Canada (Attorney General)*, 2012 FCA 92 at para. 31
[59] *Laroche v. Canada (Attorney General)*, 2013 FC 797 at paras. 7, 21, 40-46

determined earlier had such claim been issued at the appropriate time.[60]

53. Here, the Applicant is restricted to challenging whether the PMRA followed the guidance of the FCA when interpreting legislation.

The Lobby Registry

54. Specifically with respect to item 5 of the CTR Request, the Applicant suggests that there was "extensive contact" between PMRA and Monsanto / Croplife representatives, employees and lobbyists. In one of its affidavits, the Applicant lists dates of contact between Monsanto / Croplife and PMRA. This is public information available by accessing online the Registry of Lobbyists.[61]

55. However, the mere fact of contact between Monsanto / Croplife and PMRA on any number of different matters does not demonstrate bias. As noted in the *Lobbying Act*, free and open access to government is an important matter of public interest and lobbying is a legitimate activity. [62] Groups on both sides of these issues have contact with PMRA including the David Suzuki Foundation, Eco-Justice Canada, and Environmental Defence Canada.[63] Contact in and of itself between the PMRA and any group is not indicative of bias.

Contact with Various Stakeholders

56. In its Application Record, the Applicant appears to treat any points of contact, including the public consultation that took place with regards to the re-evaluation process, and the NOO at issue in this application, as one process.[64] These are separate and distinct processes. Understanding these distinctions is important in determining relevance, bias, and the overall legitimacy of the Applicant's relief sought in this motion.

57. There are key points where the *Act* requires contact between the registrant and PMRA in respect of a re-evaluation. First, the registrant must be notified that a re-evaluation is being initiated

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[60] *Behn v. Moulton Contracting Ltd.*, 2013 SCC 26 (CanLII), [2013] 2 SCR 227 at paras. 37-41
[61] *Applicant's Record*, pages 181 - 268
[62] *Lobbying Act*, R.S.C., 1985, c. 44
[63] *Aydoner Affidavit*, para. 24 and Exhibit "U"
[64] *Applicant's Record*, pages 719-720

under s. 16(3) of the *Act*.[65] This notice could include data requirements that the registrant must meet. During the re-evaluation, PMRA could issue notices requiring further information to be provided by the registrant in accordance with s. 19(1)(a) of the *Act*.[66]

58. Further, s. 19(1)(c) of the *Act* requires the Minister to consider information provided by the registrant in support of the product during an evaluation that is done in the course of a re-evaluation. Where the Minister considers additional information not provided by the registrant, the Minister must give the registrant a reasonable opportunity to make representations in respect of that information before PMRA completes its evaluation, and prior to public consultation.[67]

59. The registrant can submit comments during the public consultation required under s. 28 of the *Act* as can any other stakeholder or member of the public, including non-governmental organizations such as the Applicant.[68] While various groups generally participate in the public consultation related to a re-evaluation, the NOO decision-making process is internal to PMRA.

60. The NOO process only applies after a final re-evaluation decision is published. The fact that registrants provide information in the context of the statutory processes set out above for a re-evaluation, does not mean that this information is relevant in respect of a particular NOO or PMRA's response in respect of that NOO.

Regulatory Capture / Bias Unfounded

61. Where the courts have considered whether bias or breach of procedural fairness allegations could give rise to broader disclosure requests, they have also cautioned that these exceptions do not entitle a party to engage in a fishing expedition in the hopes of finding documents that will prove such allegations.[69]

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[65] *Act*, s. 16(3)
[66] *Act*, s. 19(1)(a)
[67] *Act*, s. 19(1)(c)
[68] *Act*, s. 28
[69] *Humane Society of Canada Foundation v. Canada (National Revenue)*, 2018 FCA 66 at para. 8 ["***Humane Society of Canada Foundation***"]

62. In *Access Information Agency Inc. v. Canada*, Justice Pelletier cautioned:

> When dealing with a judicial review, it is not a matter of requesting the disclosure of any document which could be relevant in the hopes of later establishing relevance. Such a procedure is entirely inconsistent with the summary nature of judicial review. If the circumstances are such that it is necessary to broaden the scope of discovery, the party demanding more complete disclosure has the burden of advancing the evidence justifying the request.[70]

63. The Applicant's allegations of bias and procedural fairness are based on unfounded assertions that the PMRA is incapable, lethargic, bureaucratically infirm, and may be "captured" by the very industry it seeks to regulate. The Applicant argues that the Minister must personally carry out the duties related to the NOO process.[71] In this regard, the Applicant proposes its own desired criteria as to when a review panel ought to be established, seeking that the Court provide instructions for re-considerations. In essence, asking the Court to make policy decisions.

64. In *Humane Society of Canada Foundation*, the Court stated that a bald assertion of bias is not sufficient and cannot support an order for production of documents to allow an appellant to go on a fishing expedition to see if something can be found to support the allegation of bias.[72]

65. The bias ground of review must have a factual basis supported by appropriate evidence. The party demanding more complete disclosure has the burden of advancing the evidence justifying the request. The Court is clear that this is meant to prevent an applicant raising a breach of procedural fairness simply to gain access to material that the applicant could not otherwise access.[73]

66. In *Right to Life Association*, the Court rejected the applicant's request for internal staff memoranda, even if it existed, because there was no factual basis for this demand.[74]

67. The Applicant has not advanced sufficient evidence to justify its broad request for additional documents.

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[70] *Access Information Agency Inc. v. Canada (Attorney General)*, 2007 FCA 224 at para. 21
[71] ANOA dated December 20, 2022 at para. 104
[72] *Humane Society of Canada Foundation* at para. 12
[73] *Right to Life Association of Toronto and Area v. Canada (Employment, Workforce and Labour)*, 2019 CanLII 9189 (FC) at para. 23 ["***Right to Life Association***"]
[74] *Right to Life Association* at para. 64

68. With respect to items 2 and 5 of the CTR Request, there is no basis for the allegation that the Monsanto Papers are relevant to the allegation of bias. The Applicant appears to argue that this request must be satisfied in order to show that the PMRA is not biased. This approach would reverse the burden, which requires the Applicant to advance appropriate evidence to justify the request.

69. The Supreme Court of Canada in *R. v. Mohan* established a basic structure for the admissibility of expert opinion evidence. There are four threshold requirements that the proponent of evidence must establish in order for proposed expert opinion evidence to be admissible: (1) relevance; (2) necessity in assisting the trier of fact; (3) absence of an exclusionary rule; and (4) a properly qualified expert.[75]

70. The affidavit of the purported expert, Jason MacLean, contained in the Applicant's Record is nothing more than unsubstantiated conjecture. It does not meet requirements 2 and 4 of the *Mohan* test. The affidavit is not necessary to assist the trier of fact as it goes to the very issue to be determined on judicial review: whether the PMRA was biased. Moreover, Jason MacLean is not a properly qualified expert.

71. The question of whether the PMRA was biased is one the Court is able to determine without expert assistance. Even if expert assistance was necessary, the Applicant's purported expert, Jason MacLean, does not assist the Court in determining whether the decision maker in this case was biased.

72. Secondly, he ought not to be accepted by this Court as an expert because he has not demonstrated expertise in regulatory capture and has never been qualified as an expert by any Court. His CV appears to suggest that, if he has any expertise, it would be in the area of environmental science, not regulatory capture.

73. Finally, even if the documents requested were produced, it is difficult to see how the PMRA's interpretation of the Monsanto Papers would address the question of bias.

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[75] *R. v. Mohan*, 1994 CanLII 80 (SCC), [1994] 2 SCR 9, Analysis section at paras. 20-25

Summary

74. Judicial review does not proceed on the same basis as an action. The narrow and summary nature of a judicial review is not an appropriate vehicle to address broad and overarching allegations of regulatory capture. Rule 317 does not serve the same function as documentary discovery in an action and is not a fishing expedition.

75. The question on judicial review is not whether the Applicant agrees with the interpretative approach but rather whether "the interpretation of the statutory provision is consistent with the text, context and purpose of the provision."[76]

76. While the Applicant challenges the introduction of the review panel criteria as having been completed without notice to the Applicant and consequently being procedurally unfair, the requested documents do not appear to be relevant to this issue. Nor do they demonstrate that PMRA's statutory interpretation is inconsistent with the text, context and purpose of section 35 of the *Act*. Instead, the requested documents seem to be sought to support an alternative interpretative statutory approach the Applicant advocates should be adopted.

77. The Applicant proposes that the Minister, and not a delegate, should make the decision whether to appoint a review panel and then provides criteria which the Applicant states should guide the Minister when making these decisions. Consequently, the information sought in items 2 and 5 of the CTR Request is not relevant to the procedural fairness argument. Furthermore, it does not address any of the grounds for review listed in the ANOA. As such, the requested information is irrelevant to the decision under review. Alternatively, these are arguments that could have been raised in the first judicial review.

78. The PMRA has complied with its relevant obligations under Rules 317 and 318. The materials that were before the decision maker when the decision under review was made are contained in the CTR, Volumes 1, 2 and 3.

79. Accordingly, the Applicant's motion should be dismissed.

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[76] *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65 at para. 120; *Canada Post Corp. v. Canadian Union of Postal Workers*, 2019 SCC 67 (CanLII), [2019] 4 SCR 900 at para. 42

PART IV - ORDER SOUGHT

80. The Respondents seek:

1. Dismissal of the motion;

2. Costs of the motion payable by the Applicant to the Respondents; and

3. Any other and further relief as counsel may submit, and this Honourable Court may permit.

ALL OF WHICH IS RESPECTFULLY SUBMITTED

Dated at Toronto this 8th day of June, 2023

Kathryn Hucal / Walter Kravchuk / Adrian Zita-Bennett

PART V – LIST OF AUTHORITIES

1.	*Safe Food Matters Inc v. Canada (Attorney General)*, 2022 FCA 19
2.	*Carltona Ltd. v. Commissioners of Works* [1943] 2 All E.R. 560 (C.A.)
3.	*McDonald v. Canada (Attorney General)*, 2020 FC 242
4.	*Canadian Constitution Foundation v Canada (Attorney General)*, 2022 FC 1232
5.	*Tsleil-Waututh Nation v. Canada (Attorney General)*, 2017 FCA 128
6.	*Canada (Human Rights Commission) v Pathak*, [1995] 2 FC 455
7.	*Democracy Watch v Canada (Attorney General)*, 2021 FC 1417
8.	*Athletes 4 Athletes Foundation v. Canada (National Revenue)*, 2020 FCA
9.	*Rémillard v. Canada (National Revenue)*, 2020 FC 1061
10.	*Raincoast Conservation Foundation v. Canada (Attorney General)*, 2019 FCA 224
11.	*Bernard v. Canada (Attorney General)*, 2012 FCA 92
12.	*Laroche v. Canada (Attorney General)*, 2013 FC 797
13.	*Behn v. Moulton Contracting Ltd.*, 2013 SCC 26 (CanLII), [2013] 2 SCR 227
14.	*Humane Society of Canada Foundation v. Canada (National Revenue)*, 2018 FCA 66
15.	*Access Information Agency Inc. v. Canada (Attorney General)*, 2007 FCA 224

16.	*Right to Life Association of Toronto and Area v. Canada (Employment, Workforce and Labour)*, 2019 CanLII 9189 (FC)
17.	*R. v. Mohan*, 1994 CanLII 80 (SCC), [1994] 2 SCR 9
18.	*Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65
19.	*Canada Post Corp. v. Canadian Union of Postal Workers*, 2019 SCC 67 (CanLII), [2019] 4 SCR 900