Court File No. T-2292-22

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.

Applicant

and

THE ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

WRITTEN REPRESENTATIONS OF THE APPLICANT
(Rule 318 Application)

Counsel for the Applicant:	**Counsel for the Respondents:**
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PART I: STATEMENT OF FACTS

Overview

1. The Applicant applies under Rules 317 and 318 of the Federal Court Rules to compel the Respondent to file a supplemental Certified Tribunal Record consisting of the following categories of documents:

    a. All documents dealing with interactions between the Respondent and Monsanto/Bayer, Croplife and JGTF that relate to the reapproval of Glyphosate and the Respondent's decision not to appoint an independent scientific review panel;

    b. Unredacted versions of the Glyphosate Memoranda at Tabs 40 and 42 of Volume I of the Certified Tribunal Record; and

    c. All documents dealing with the Respondent's response to the "Monsanto Papers".

Procedural Background

1. The Applicant filed a Notice of Application on October 31, 2022. The Application seeks judicial review of the refusal of the Pest Management Regulatory Agency ("PMRA"), which is a division of the Ministry of Health, to appoint an independent review panel pursuant to s.35 of the *Pest Control Products Act*, S.C. 2002 c.28 (the "*Act*"), and s.3(b) of the *Review Panel Regulations*, (SOR 2008/22) (the "*Regulations*").

2. The decision not to appoint an independent review panel is in respect of a re-evaluation decision of the Respondent made in 2017 to renew the registration of Glyphosate as a pesticide on the basis that did not impose undue risk to human health. Glyphosate is the most widely used herbicide in Canada. The re-evaluation process commenced in 2009.

    Safe Food Matters Inc. v. Canada (Attorney General), 2022 FCA 19 (CanLII) at paras.4-6.

3. This judicial review is of a reconsideration decision that follows the Federal Court of Appeal decision indexed as *Safe Food Matters Inc. v. Canada (Attorney*

General), 2022 FCA 19 (CanLII). The Federal Court of Appeal provided guidance at paragraph 65 and suggested that the PMRA have regard to the specific role and purpose of a review panel with the composition set out in the *Regulations*, in contrast to the role and purpose of the PMRA, when it receives a notice of objection under s.35(1) of the *Act*, as well as the criteria for determining whether the advice of an independent expert panel would assist the Minister.

4. Given the need to render a statutory interpretation of the institutional relationship between the PMRA and an independent review panel, the Certified Tribunal Record ("CTR") must include documents of sufficient breadth to allow the Court to apply s.35 of the *Act* and s.3 of the *Regulations*.

5. The Amended Notice of Application sets out legal argument from paragraphs 94 to 177 that advance an interpretation of s.35 of the *Act* and s.3 of the *Regulations*. The Applicant argues that the *Act* requires the Minster to consider whether fulfilment of statutory functions would be enhanced by the appointment of an independent expert review panel, having regard to the current and historical relationship between PMRA and the regulated entity, and the public perception thereof, among other factors.

6. Interpreting s.35 of the *Act* and s.3 of the *Regulations*, as the Court of Appeal sets out at para.65, 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.

7. 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. Parliament intended to ensure that the Minister has a resource other than scientists within PMRA in deciding whether to confirm, reverse or vary a registration, re-evaluation or special review decision of the PMRA.

8. The Applicant says that 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.

9. The Applicant proposes a test for appointing an independent review panel that would have the Minister 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 factors 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.

10. 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 PMRA, 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.

11. 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.

Item A – Monsanto/Bayer/Croplife Submissions on Glyphosate

12. The Respondent engaged in an administrative decision-making process in respect of Glyphosate. Monsanto/Bayer is the manufacturer and distributor of Roundup/Glyphosate products. Croplife is the leading pesticide industry advocacy organization. JGTF, or Joint Glyphosate Task Force, is an umbrella group of 26 corporations including Monsanto/Bayer. Monsanto/Bayer, Croplife and JGTF almost certainly made submissions to PMRA about whether the registration of Glyphosate should be renewed and under what conditions.

13. The Applicant sets out a significant body of evidence supporting the proposition that Monsanto/Bayer and Croplife made submissions to PMRA regarding the renewal of the Glyphosate registration and the appointment of an independent scientific review panel.

14. Firstly, the 2017 Re-evaluation Decision, attached as Exhibit A to Affidavit #1 of Mary Lou McDonald, repeatedly acknowledges the submissions made by registrants including Monsanto/Bayer, (e.g. "Re-evaluation draws on data from registrants...", "Registrant-supplied short and long term (lifetime) animal toxicity tests... were assessed").

Affidavit #1 of ML McDonald, Ex.A., pp.7 and 8

15. The 2017 Re-evaluation Decision also makes repeated reference to "JGTF" submissions, without defining the composition of JGTF. JGTF is an industry group consisting of Glyphostate registrants including Monstanto/Bayer. The JGTF submissions relate principally to whether Glyphosate is carcinogenic, immunotoxic or genotoxic. Joint Glyphosate Task Force, LLC, is formally noted as a registrant.

Affidavit #1 of ML McDonald, Ex. A, pp.17, 20-22, 29, 67

16. Secondly, documents printed from Canada's Lobbying Registry set out extensive contacts between senior PMRA employees and lobbyists representing Monsanto/Bayer and Croplife. The records appended as exhibits to Affidavit #3

of J Kaldestad show extensive contacts between the following:

a. Pierre Patelle, President and CEO of CropLife Canada, and the Executive Director of PMRA;

b. Michiel de Johgh, President and General Manager of Monsanto Canada, and numerous representatives of the government of Canada;

c. Alok Kanti, President and Chief Executive Officer of Bayer Inc, and numerous representatives of Health Canada; and

d. Al Driver, President and CEO of Bayer CropScience Inc. (who is on the Board of Directors of CropLife Canada) and numerous representatives of Health Canada, including the Executive Director of PMRA.

Affidavit #3 of J Kaldestad

17. Thirdly, annual reports of Croplife assert that they have repeatedly communicated with PMRA. The following are quotes from Croplife's Annual Report for 2020-2021, which is appended to Affidavit #2 of J Kaldestad at Ex.Q (p.117):

> We identified and explored issues and opportunities related to the Pest Management Regulatory Agency's re-evaluation program and advocated for a renewed approach based on efficiency, predictability and transparency... (p.121)
>
> [A Year in Numbers:] More than 275 meetings with federal and provincial government officials... (p.123)
>
> The PMRA program renewal (formerly known as re-evaluation process reform) continued to be a high priority for CropLife Canada in the past year. ... We provided significant input to the PMRA on its proposal through two CropLife Canada-hosted government/industry sessions. We also developed a program renewal white paper to summarize the industry's input toward a more efficient, transparent and predictable regulatory program for pesticides. (p.124)
>
> Recognizing the importance of international trade for the Canadian agricultural sector, CropLife Canada has provided leadership in advocating for more cooperation and alignment in pesticide regulations between Canada and the United States. Of note is our support to the work of the Trilateral Working Group on Pesticides and participation in the PMRA's new iMRL project aimed to facilitate the use of foreign reviews. (p.126)

> Over the winter, CropLife Canada submitted three substantial documents: a labelling report, a whitepaper on program renewal and a cancellation/amendment discussion paper to the PMRA. Staff also commented on a PMRA pre-consultation related to the Pest Control Products Regulation (PCPR). (p.129)
>
> In May, CropLife Canada's government affairs committee held its annual lobby week. Through the virtual blitz, we had 13 meetings with members of parliament from both government and opposition along with senior political staff and senators to discuss regulatory modernization, sustainability, funding for the PMRA and agriculture's role in the post-COVID recovery.

18. The following are quotes from Croplife's Annual Report for 2021-2022, which is appended to Affidavit #2 of J Kaldestad at Ex.R (p.144):

> At the same time, we saw the Government of Canada unleash a "Transformation Agenda" as it relates to the work of the Pest Management Regulatory Agency. This agenda, which threatens to undermine the very science-based nature of the regulatory system, was driven in large part by activist pressure... (p.145)
>
> In the summer of 2021, a politically motivated decision triggered the launch of what Health Canada call the Pest Management Regulatory Agency (PMRA) Transformation Agenda. To guide this transformation agenda Health Canada published Discussion Document DIS2022-01. Further Strengthening Protection of Health and the Environment: Targeted Review of the Pest Control Products Act (PCPA), for consultation. In concert with the publication of his discussion document, the PMRA established a transformation steering committee (TSC) and a number of multi-stakeholder technical working groups (TWG), which included CropLife Canada's suggestion for an MRL TWG, to provide additional context to the various aspects presented in the consultation document and seek early feedback on several new proposed initiatives.
>
> CropLife Canada staff, along with member representatives, participated in six PMRA established working groups. In total, CropLife Canada participated in 20 TSC and TWG meetings between March and June, with more to come in the fall of 2022. This work, in close coordination with CropLife Canada's PCPA project team, culminated in a 32-page submission in response to the consultation document. In the submission, CropLife Canada stated its position that the PCPA remains fit for purpose and that any enhancements required for increased efficiency or transparency can be achieved without legislative changes. CropLife Canada will continue to provide industry leadership on the Transformation Agenda, including timely science-based input to the PMRA. (p.149).

> In early 2022, the PMRA announced the creation of a Science Advisory Committee to "provide advice, as appropriate, prior to certain evidence-based federal decisions on pesticides, including on pesticide Maximum Residue Limits (MRLs)". CropLife Canada responded to this announcement with a submission to the PMRA, a position statement as well as several media interviews. An additional statement expressing concerns about the process and appointments to the committee was posted publicly on the CropLife Canada website. (p.150).
>
> In total, eight submissions were made to various government departments: ... The formation of the Science Advisory Committee on pest control products. (p.152)

19. An analysis of LinkedIn postings shows that a significant proportion of Croplife's senior employees were previously employed by Health Canada (including PMRA), CFIA, Global Affairs Canada, Agriculture and Agri-Foods Canada, and other government positions. Pierre Petelle, the President and CFO of Croplife, for example, worked for PMRA as a Senior Policy Analyst from 2003 to 2008.

    Affidavit #2 of J Kaldestad, Ex. A.

20. It can only be concluded that Glyphosate registrants and their agents, including Monsanto/Bayer, CropLife and JRTF, made repeated submission to the Respondent, and that the Respondent had regard to these submissions when determining to re-approve Glyphosate and refusing to appoint an independent science review panel. These submissions were considered by the Respondent and should be available to the Court.

Item B - Unredacted versions of the Glyphosate Reports at Tabs 40 and 42 of Volume I of the Certified Tribunal Record

21. The Applicant seeks unredacted versions of the Glyphosate Reports at Tabs 40 and 42 of Volume 1 of the CTR. Tab 40 is a memorandum authored by Haris Gosavi entitled "Toxicology Monograph: Toxicology Assessment", dated March 31, 2015. Tab 42 is an undated memorandum authored by Haris Gosavi entitled "Evaluation of Fetal Cardiovascular Effects" (the CTR index gives March 20, 2017 as a reference date).

    Affidavit #4 of Jodi Kaldestad, affirmed May 29, 2023

Item C - All documents dealing with the Respondent's response to the "Monsanto Papers".

22. The "Monsanto Papers" are a series of internal Bayer/Monsanto documents produced in response to multi-district litigation commenced against Monsanto in the United States. The Monsanto Papers include internal company communications, communications between company employees and external parties (including regulators), private studies (including discontinued and nondisclosed studies disclosing harmful effects of glyphosate), presentations and reports.

Expert Report and Affidavit of Prof. MacLean, p.22, para.41

23. The Monsanto Papers reveal Monsanto's efforts to capture the regulation of glyphosate and its Roundup products, including "ghostwriting" of ostensibly independent academic papers. The ghostwritten papers are signed by seemingly independent academics largely written, edited and controlled by Monsanto scientists who are not listed as authors. The papers are supportive of glyphosate and critical of independent, peer-reviewed research that questions the safety of glyphosate to human health. The Monsanto Papers demonstrate a pattern by Monsanto of engaging in low integrity science.

Expert Report and Affidavit of Prof. MacLean, p.23, para.41

24. The Monsanto Papers also disclose a very close and cooperative relationship between Monsanto and PMRA. The PMRA has not publicly responded to the Monsanto Papers but has not disavowed its reliance on the ghostwritten independent academic papers and other data and reports provided by Monsanto, despite the inference to unreliability and lack of integrity of the "science" behind Monsanto's submissions.

Expert Report and Affidavit of Prof. MacLean, p.23, paras.44 and 55

PART II: STATEMENT OF POINTS IN ISSUE

The following is the point in issue on this application:

1. Should the Respondent be required to file a supplemental Certified Tribunal Record consisting of the following categories of documents:

    a. All documents dealing with interactions between the Respondent and Monsanto/Bayer, Croplife and JGTF that relate to the reapproval of Glyphosate and the Respondent's decision not to appoint an independent scientific review panel;

    b. Unredacted versions of the Glyphosate Memoranda at Tabs 40 and 42 of Volume I of the Certified Tribunal Record; and

    c. All documents dealing with the Respondent's response to the "Monsanto Papers".

PART III: STATEMENT OF SUBMISSIONS

Legal basis

1. Rules 317 and 318 provide a means to ensure that the record before the Court is the same record as was before the Tribunal. The material requested under Rule 317 should be relevant to grounds of review set out in the Notice of Application. A document is relevant if it may affect the decision the Court will make.

    Canada (Human Rights Commission) v. Pathak, 1995 CanLII 3591 (FCA)

2. The breadth of materials that are subject to disclosure under Rule 317 is broader when bias or breach of procedural fairness is alleged. In such circumstances, documents relevant to bias are relevant and should be produced.

    Air Passenger Rights v. Canada (Attorney General), 2021 FCA 201

3. In this case, the first category of documents is the submissions of the companies

that are registrants of Glyphosate products and their agents (Monsanto/Bayer, CropLife and JGTF), in respect of the process for reapproval of Glyphosate and the appointment of an independent review panel under s.35 of the *Act*. This is a narrow request relating to materials that were considered by the PMRA in its decision-making.

4. The second category of documents deals with unredacted memoranda. Ordinarily, memoranda prepared for a decision-maker where the memoranda may have affected the decision of the tribunal ought to be included in the CRT.

Telus Communications Inc. v. Canada (Attorney General), 2004 FCA 317.

5. The Respondent has refused to provide these reports on the spurious basis that counsel for Safe Food Matters, on a previous judicial review, did not take issue with the redactions. That objection is of no merit.

6. The Respondent says that the redactions are supportable as confidential business information and confidential test data. The Applicant objects to this purported justification for redaction on the basis that it has no foundation in law.

7. The *Act* offers the following definitions:

> *confidential business information* means information to which access may be refused under the *Access to Information Act* and that meets the requirements of subsection 43(4) or (5). (renseignements commerciaux confidentiels)
>
> *confidential test data* means test data to which access may be refused under the *Access to Information Act*. (données d'essai confidentielles)
>
> 43(4) Subject to subsections (5) and (6), confidential business information is information provided under this Act that is designated as confidential business information by the person who provided it, or information provided under the *Pest Control Products Act*, chapter P-9 of the Revised Statutes of Canada, 1985, and that concerns

> (a) manufacturing or quality control processes relating to a pest control product;
>
> (b) methods for determining the composition of a pest control product; or
>
> (c) the monetary value of sales of pest control products provided to the Minister pursuant to subsection 8(5) and other financial or commercial information provided to the Minister pursuant to this Act or the regulations.

8. There is no indication that the redactions to the memoranda under Tabs 40 or 42 concern "confidential business information" within the meaning of s.43(5) of the *PCPA*. In particular, there is no indication that the information is designated as confidential by the person who provided it, or that it relates to manufacturing or quality control, methods for determining composition, or the monetary value of sales.

9. Section 67(1)(m) allows for the enactment of regulations dealing with protection of confidential test data, but the *Pest Control Products Regulations* contain no legal authority that would lend support to the Respondent's redactions. The only glancingly relevant provisions establish a compensation scheme that would entitle the original registrant to compensation if another registrant wishes to rely on that test data within 10 years of the initial registration.

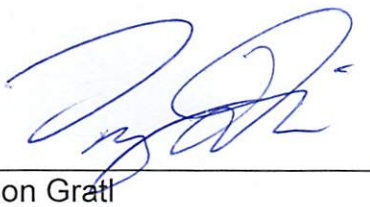
10. The burden of proving the existence of a privilege rests with the party asserting the privilege. Evidence must be filed where the facts are in dispute. To verify the existence of a privilege, the judge may examine the document, but is not required to do so. Where an affidavit is filed setting out the factual basis for the claim to privilege, the judge may rely on that affidavit. In this case, there is no such affidavit.

> *Parker v. Canada (Attorney General)*, 2021 FC 496
> *Girouard v. Canada Judicial Council*, 2019 FCA 252
> *Bernard v. PSAC*, 2017 FCA 35

11. In sum, the redactions made to the memoranda under Tabs 40 and 42 are without legal or factual foundation. They cannot be justified.

12. The third category of documents sought for inclusion in the CTR is all documents dealing with the Respondent's response to the "Monsanto Papers". The Monsanto Papers set the social context for PMRA's relationship with the primary registrant of Glyphosate in Canada. The Monsanto Papers concern the integrity of the scientific analysis in which PMRA engaged and the proximity and nature of the relationship between PMRA and Monsanto/Bayer. These matters are a central consideration for the Minister in determining whether an independent scientific review panel is appropriate. PMRA's relationship with Monsanto and its response to the questions raised by the Monsanto Papers to the scientific integrity of the science submitted by Monsanto was undoubtedly among the considerations that ought to have been considered by the Minister in determining whether to appoint an independent scientific review panel.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 29th day of March 2023.



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