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Court File Number: T-277-19

FEDERAL COURT

FEDERAL COURT
COUR FÉDÉRALE
FILED
FEV FEB 11 2019
DÉPOSÉ
Kevin Lemieux
CALGARY, AB

MARY LOU MCDONALD and SAFE FOOD MATTERS INC.

(Applicants)

and

ATTORNEY GENERAL OF CANADA

(Respondent)

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 SIGNÉL'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

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c/o Deputy Attorney General of Canada
Office of the Deputy Attorney General of Canada
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AND TO:
Pest Management Regulatory Agency
Health Canada
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Address locator
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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.
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