Federal Court  Cour fédérale

Date: 20200213

Docket: T-277-19

Citation: 2020 FC 242

Ottawa, Ontario, February 13, 2020

PRESENT: Madam Justice Simpson

BETWEEN:

MARY LOU MCDONALD
AND SAFE FOOD MATTERS INC.

Applicants

and

ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

[1] This application is for judicial review of a decision of the Pest Management Regulatory Agency dated January 11, 2019 [the Decision], in which it decided not to establish a panel of scientists to review its earlier decision, made in 2017, to permit the continued registration of glyphosate products in Canada. This application was brought pursuant to subsection 18.1(1) of the *Federal Courts Act*, R.S.C. 1985, c. F-7. The Applicants request an order quashing the Decision, and directing the PMRA to establish a review panel or in the alternative, remitting the

question of whether to establish a review panel back to the PMRA for reconsideration in accordance with any direction given by the Court.

I. The Parties

[2] The Applicants are Mary Lou McDonald and Safe Food Matters. Safe Food Matters is a non-profit corporation dedicated to promoting health and protecting the environment through education, awareness and the engagement of Canadians about the safety of food production technologies. Mary Lou McDonald is the President of Safe Food Matters.

[3] In practice, the Respondent is the Pest Management Regulatory Agency [PMRA]. It is the branch of Health Canada responsible for regulating the use of pest control products in Canada in a manner that protects the health and safety of Canadians. The PMRA acts on behalf of the Minister of Health with respect to the regulation of pesticides in Canada under the *Pest Control Products Act*, S.C. 2002, c. 28 [the PCP Act].

II. The Standard of Review

[4] In *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65 [*Vavilov*], the Supreme Court of Canada states at paragraph 16 that for all administrative decisions, there is a presumption that the standard of review is reasonableness. At paragraphs 17 and 70, the Court indicates that the standard of review will only be correctness if legislation prescribes it, or if the matter falls into one of the following categories: it raises a Constitutional question; it raises a question of central importance to the legal system as a whole; it raises a question about the jurisdictional lines to be drawn between tribunals; or where a failure to apply correctness review would undermine the rule of law and jeopardize the proper function of the justice system in a manner analogous to one of the above three categories.

[5] Here, the PCP Act does not prescribe the correctness standard, and the matter does not fall into any of the correctness categories. Accordingly, reasonableness is the standard of review and both parties agree with this conclusion.

III. The Procedural Background

[6] There is no dispute that glyphosate is a pest control product governed by the PCP Act. In addition to being a weed-killer, glyphosate is a desiccant. It is used to facilitate harvesting by killing crops just before harvest so that they dry quickly and evenly in the field.

[7] Glyphosate was first registered for use in Canada in 1976. In 2005, the PMRA gave approval to a label expansion which allowed it to be used as a pre-harvest desiccant on a variety of crops including chickpeas.

[8] In 2009, the PMRA gave notice of its intention to re-evaluate glyphosate. On April 13, 2015, the PMRA issued a Proposed Re-Evaluation Decision [the Proposed Re-Evaluation] and the subsequent Re-Evaluation Decision was dated April 28, 2017 [the Re-Evaluation]. These two documents will be described collectively as the "Evaluations". The Evaluations were the basis for the decision to permit the continued registration of glyphosate.

[9] The Proposed Re-Evaluation is described as follows in passages which are found under the heading "Overview":

> An 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. As a condition of the continued registration of glyphosate uses, new risk reduction measures are proposed for the end-use products registered in Canada. No additional data are being requested at this time.
>
> . . .

> This Proposed Re-evaluation Decision is a consultation document that summarizes the science evaluation for glyphosate and presents the reasons for the proposed re-evaluation decision. It also proposes new risk reduction measures to further protect human health and the environment.
>
> The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of glyphosate.
>
> The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).
>
> . . .
>
> [Footnote omitted]

The Applicants provided written comments and participated in the public consultation process based on the Proposed Re-Evaluation.

[10] In due course, the Re-Evaluation was published. Its Executive Summary reads in part as follows:

> During this re-examination, the PMRA assessed the potential human health risk of glyphosate from drinking water, food, occupational and bystander exposure, as well as the environmental risk to non-target organisms. Both the active ingredient and formulated products were included in the re-evaluation. The assessment was carried out based on available information provided by the manufacturer of the pesticide, as well as a large volume of published scientific literature, monitoring information (for example, ground water and surface water) and reviews conducted by other regulatory authorities.
>
> The overall finding from the re-examination of glyphosate is highlighted as follows:
>
> - Glyphosate is not genotoxic and is unlikely to pose a human cancer risk.

- Dietary (food and drinking water) exposure associated with the use of glyphosate is not expected to pose a risk of concern to human health.

- Occupational and residential risks associated with the use of glyphosate are not of concern, provided that updated label instructions are followed.

- The environmental assessment concluded that spray buffer zones are necessary to mitigate potential risks to non-target species (for example, vegetation near treated areas, aquatic invertebrates and fish) from spray drift.

- When used according to revised label directions, glyphosate products are not expected to pose risks of concern to the environment.

- All registered glyphosate uses have value for weed control in agriculture and non-agricultural land management.

[11] The Re-Evaluation also commented on the study and use of glyphosate in other jurisdictions. In this regard, the PMRA stated at pages 8 and 9:

> The PMRA routinely works collaboratively with other member countries within the Organisation for Economic Co-operation and Development (OECD) on the regulation of pesticides. As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of a pesticide in other jurisdictions. Glyphosate is currently acceptable for use in other OECD countries, including the United States, Australia and the European Union. As of 8 March 2017, no decision by an OECD member country to prohibit all uses of glyphosate for health or environmental reasons has been identified.
>
> In March, 2015, the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) published a summary of results of their hazard classification of five pesticides, including glyphosate. IARC classified glyphosate as probably carcinogenic to humans. It is important to note that the IARC classification is a hazard classification and not a health risk assessment. This means that the level of human exposure, which determines actual risk, was not taken into account by IARC.
>
> In November, 2015, the European Food Safety Authority (EFSA) finalized their re-assessment of glyphosate, concluding that

> glyphosate is unlikely to pose a carcinogenic hazard to humans. The EU also set an acute reference dose, which is the same as that set by the PMRA (PRVD2015-01). In May 2016, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) concluded that glyphosate is unlikely to be genotoxic at anticipated dietary exposures and that it is unlikely to pose a carcinogenic risk to humans from exposure through the diet. In March, 2017, the European Chemical Agency (ECHA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) released their determination that glyphosate is not a carcinogen. Currently, no pesticide regulatory authority, including Health Canada, considers glyphosate to be a carcinogenic risk of concern to humans.
>
> [My Emphasis]

The Re-Evaluation invited the public to file Notices of Objection.

[12] Section 35 of the PCP Act permits the filing of a Notice of Objection [NOO]. It reads as follows:

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**
(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	(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

authorization within 60 days after a notice referred to in subsection 33(6) or 34(4) is made public.

à la décision d'autoriser l'exportation d'un produit antiparasitaire ou de modifier ou de révoquer l'autorisation d'exportation.

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.

Constitution d'une commission d'examen

(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

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

Avis — commission d'examen

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

Reasons to be provided if panel not established

(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

(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

(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

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

Representations	**Observations**
(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.	(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	**Accessibilité**
(8) Subject to subsections 44(3) and (6), the hearings of a review panel shall be open to the public.	(8) Sous réserve des paragraphes 44(3) et (6), les audiences de la commission sont publiques.
Information to be placed in Register	**Inscription au Registre**
(9) A review panel shall give the information submitted to it to the Minister, who shall place it in the Register.	(9) Les renseignements fournis à la commission sont remis au ministre, qui les verse au Registre.

[13] The Applicants filed an NOO asking that a review panel be established to review the decision to continue glyphosate's registration. The NOO raises concerns about the use of glyphosate as a pre-harvest crop desiccant, not as a weed killer, and the focus of the concerns expressed is harm to humans, not harm to the environment.

[14] Section 3 of the Review Panel Regulations (SOR/2008-22) to the PCP Act [the RP Regulations] states:

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,	**a)** l'avis d'opposition soulève un doute, sur la base de renseignements fondés scientifiquement, quant à la validité des

on which the decision was based, of the health and environmental risks and the value of the pest control product; and	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.
[My Emphasis]	[Non souligné dans l'original]

[15] Section 4 of the RP Regulations provides that a review panel must be composed of independent scientists who have the expertise necessary to evaluate the subject matter of the objection in the NOO:

Review Panel Composition	**Composition des commissions d'examen**
4 If the Minister determines that it is necessary to establish a review panel of one or more persons, each person selected by the Minister shall	**4** Si le ministre décide de constituer une commission d'examen composée d'une ou de plusieurs personnes, il choisit chacune d'elles en fonction des critères suivants :
(a) possess scientific knowledge that allows them to evaluate the subject matter of the objection;	**a)** elle possède des connaissances scientifiques de nature à lui permettre d'évaluer l'objet de l'opposition;
(b) 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 as set out, respectively, in Schedules I, I.1, II and III to the *Financial Administration Act*, within	**b)** elle n'a, dans l'année précédant sa nomination comme membre de la commission d'examen, été employée dans aucun ministère ou secteur de l'administration publique ni au sein d'aucune personne morale ou société d'État mère respectivement visés aux annexes I, I.1, II

one year before the day on which they are appointed to the review panel;	ou III de la *Loi sur la gestion des finances publiques*;
(c) have provided the Minister with a written statement indicating that they are free from any actual or potential conflict of interest that relates to the decision under review; and	**c)** elle a fourni au ministre une déclaration écrite portant qu'elle n'est pas en conflit d'intérêts réel ou potentiel par rapport à la décision contestée ;
(d) have undertaken in writing to disclose to the Minister in writing, without delay, any actual or potential conflict of interest that may arise and affect their duties as a member of the review panel.	**d)** elle s'est engagée par écrit à signaler sans délai au ministre, également par écrit , tout conflit d'intérêts réel ou potentiel susceptible de survenir dans le cadre de ses fonctions à titre de membre de la commission.

IV. The Decision

[16] In its Decision not to establish a review panel, the PMRA found that the Applicants' NOO did not meet either of the criteria set out in Section 3 of the RP Regulations. In other words, the NOO did not raise scientifically founded doubt about the validity of the Evaluations and expert scientists would not be able to assist in addressing the topics raised in the NOO. As part of the Decision the PMRA provided a response to the issues raised in the NOO [the Response]. The Response will be described below when the issues are discussed.

V. Scientifically Founded Doubt

[17] There are no cases which consider the meaning of this concept. However, in opening submissions, the Applicants acknowledged and I agree that decisions under the PCP Act are to be based on rigorous science. In my view the NOO process under the Act is also to be underpinned by rigorous science. Moreover, sections 3 and 4 of the RP Regulations, which are

set out above, make it clear that the purpose of the NOO in this case is to challenge the science relied on by the PMRA in the Evaluations which support the decision to continue the registration of glyphosate. In my view, the NOO is not a vehicle for challenging the Evaluations for reasons that have no scientific basis.

[18] The context signals to me that this is the correct approach. The challenge to the science in the NOO, if accepted, would result in the appointment of a panel of independent scientists. Based on scientific principles, the panel would provide the PMRA with recommendations which would either confirm or question the PMRA's decision about the continued registration of glyphosate.

[19] Given this context, the Decision not to appoint a review panel will be unreasonable only if the Applicants' NOO shows a well founded scientific doubt about a conclusion in the Evaluations. It is also my view 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.

[20] Contrary to the Applicants' submissions, I am not prepared to find that a scientifically founded doubt can arise based on a newspaper article or because there is an absence of studies on a topic or because scientists have written articles expressing their opinions. Articles of this kind are part of the literature on a topic and are significant because they raise interest in an issue and may lead to the funding of a study. However, neither an absence of studies nor published opinions create a scientifically founded doubt in the world of rigorous science.

[21] The Applicants were not required to use the NOO procedure. The decision to continue the registration of glyphosate could have been challenged on judicial review for being unreasonable. In such a challenge there would have been no requirement to show scientifically founded doubt.

VI. Background Information

A. *Translocation*

[22] When applied to a crop in which seeds and fruits are still growing, glyphosate will move to and build up as residue in those parts of the plant. The PMRA establishes maximum residue limits (MRLs) for glyphosate in many crops. At page 4 of the Response, PMRA states that MRLs are set well below levels that would present a human health concern.

B. *Crop Moisture content and Maturity*

[23] The PMRA has directed that glyphosate is only to be applied when the moisture content of the plants in a crop is below 30%. Farmers are directed to visually inspect the crop to determine if certain indicia of maturity and moisture content which are described on a label (such as brown stems or seeds) are present.

C. *Exceedances*

[24] If a crop is tested and levels above MRLs are detected, such levels are called Exceedances. Exceedances may not be problematic because the residue levels, while above the MRLs, may nevertheless be well below levels that pose a health risk.

D. *Indeterminate Crops*

[25] Crops in which the entire plant matures at the same time are called determinate crops. Other crops may be indeterminate in that they grow continually. This means that, even at harvest time, parts of the plant may be immature. Accordingly when glyphosate is applied as a preharvest desiccant, residue levels may be present due to translocation. Chickpeas and lentils are indeterminate crops.

E. *Crop Groups*

[26] PMRA does not assign MRLs to all crops. Instead similar crops are grouped together and a representative crop is selected. Its MRL is applied to all the crops in the group. As a result of a field trial study conducted in 1992 [the 1992 Study], white beans are the representative crop for the group that includes chickpeas.

[27] In the Affidavit of Isabelle Pilote, affirmed on June 27, 2019 [the Pilote Affidavit] at paragraphs 58 and 59, the PMRA explains crop grouping as follows:

> Crop groupings are used in many countries around the world and allow for crop field 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 what part of the crop is edible (e.g. the beans inside the bean pods of bean plants). From the crops listed in a crop group, between two and seven crops are chosen to be representative of the entire group. A representative crop is most likely to contain the highest pesticide residues, is based on both professional expertise and supporting data, and is also likely to be a major crop in terms of production and/or consumption.

VII. The Issues

[28] In the NOO, the Applicants raised the following issues:

1) Regarding Residue Levels and Exceedances: information from the Canadian Food Inspection Agency and other sources regarding translocation and the impact of crop immaturity on residue levels raises scientifically founded doubt about the validity of the Evaluations' conclusion that glyphosate is not expected to pose a risk to human health;

2) Regarding the Dietary Consumption Data: the PMRA relied on US data from 1998 and did not meaningfully consider more recent 2010 dietary consumption data;

3) Regarding the Margin of Exposure: the application rate variable in a study of glyphosate exposure in rats was inappropriately reduced by the PMRA from twice to once in a seven day period; and

4) Regarding the Safety or PCPA Factor: the safety factor in a study of rabbits was inappropriately reduced from 10-fold to 3-fold.

A. *Issue I – Residue Levels and Exceedances*

[29] In the Response the PMRA rephrased the concerns the Applicants had expressed in the NOO and described them as comments. It then provided responses. On this issue, the four comments were as follows:

> Comment 2: A comment was received which indicated that the early application of glyphosate as a desiccant or the application of glyphosate when moisture content is too high resulted in exceedances of the Maximum Residue Limits (MRLs) for some crops. It also referenced data obtained from the Canadian Food Inspection Agency (CFIA), which showed exceedances in a cereal and legume. Safe Food Matters Inc. states that since food containing a pesticide residue that does not exceed the established MRL does not pose a health risk concern; foods that do exceed the established MRL do pose a health risk and thus endanger human health.
>
> Comment 3: A comment was received which 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 that mechanisms by

> which MRLs can be exceeded in desiccated crops, [*sic*] and that data from the CFIA indicates that exceedances are occurring.
>
> Comment 5: A comment was received which referenced the 2017 Guide to Crop Protection published by the Saskatchewan Ministry of Agriculture, which stated that the use of glyphosate for the use of "Crop Staging for Preharvest 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.
>
> Comment 6: A comment was received which 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 because of the subjective content of any label and the unpredictability of the weather which can affect moisture content

[30] The Applicants say that in writing these comments, PMRA understated their concerns. They say that a concern about the application of glyphosate to plants with a moisture content above 30% is not the only issue they expressed in the NOO. They state that, in the NOO, they also expressed concern that moisture levels do not necessarily indicate crop maturity. They further state that the PMRA failed to address the relevant study in the Response.

[31] A review of the NOO shows that the only reference to crop maturity is found in the paragraph below and, in my view, it was simply a description of translocation in immature plants.

> The literature indicates when glyphosate is applied to crops that have already emerged, it translocates to seeds of the plant. Moreover, the earlier glyphosate is applied as a desiccant, or the more moisture content there is in the plant, the higher the residue levels in the plant. This is because glyphosate moves preferentially to growing points, which are largely the seed. If glyphosate is applied to a crop that is not physiologically mature, it accumulates more in the seed.
>
> [My Emphasis]

[32] Accordingly, I have found that the NOO narrative did not raise the question of whether moisture content is a reliable indication of crop maturity.

[33] However, in footnote 4 to the NOO, the Applicants submitted the Cessna Canola Study [the Canola Study]. It does suggest that moisture content alone is not a reliable indicator of crop maturity. However, it concludes that a moisture content below 30% plus a visual assessment of the crop is reliable methodology and, since that is what is directed on the glyphosate labels in the record, there is no scientifically founded doubt raised by this study about the adequacy of the current directions for the use of glyphosate. In my view given that the Response indicates at page 4 that the PMRA assessed the scientific literature submitted with the NOO and given that the Canola Study did not contradict the Evaluations, there was no need to discuss it in detail in the Response.

[34] I turn now to the 2016 CFIA data mentioned in Comment 2 [the CFIA Data] and note that chickpeas are the crop which concerns the Applicants in this context.

[35] The Re-Evaluation provides background on this issue at page 9. It reads:

> Health Canada's PMRA sets Maximum Residue Limits (MRLs) for pesticide residues on food, which is the maximum amount of residue that is expected to remain on food products when a pesticide is used according to label directions. These are set at levels well below the amount that could pose a health concern. In 2015, the Canadian Food Inspection Agency (CFIA) tested approximately 700 samples consisting of a variety of juice and juice blends, grains and grain products, beans, lentils, and a variety of fruit and vegetables. The CFIA also initiated a targeted survey of approximately 2,500 samples, looking at levels of glyphosate in bean, pea, lentil, chickpea and soy products, as well as less commonly consumed grains such as barley, buckwheat and quinoa. The results show a high degree of compliance with the MRLs established by the PMRA for glyphosate. The CFIA anticipates having the full analysis completed by Spring 2017.

[36] The CFIA eventually concluded that glyphosate residues above MRLs were found in only 1.3% of 3,188 samples and that no human health concerns were present. The samples included chickpeas.

[37] The CFIA Data were provided to the Applicants with an email dated January 16, 2019. They show that the CFIA identified 2 Exceedances in 93 observations of chickpeas and concluded that neither posed a risk to human health. Accordingly, there is no scientifically founded doubt about the safety of glyphosate in chickpeas.

[38] The Applicants also expressed concern about white beans as the representative crop for chickpeas. They submit that the PMRA failed to consider the risk that chickpeas will contain unacceptable glyphosate residues due to translocation. The Applicants submit that chickpeas are particularly susceptible to glyphosate MRL exceedances because as an indeterminate crop, they will always have immature seeds. The Applicants state that chickpeas should not be in a crop

group with white beans as the representative crop, because white beans, unlike chickpeas, are determinate.

[39] The Respondent submits that there is no scientific basis for saying that there is a problem with grouping chickpeas in a crop group with white beans. The Respondent cites the CFIA Data described in paragraph 36 above that showed that the percentage of MRL exceedances was low and that the non-compliant data did not pose a health risk. It is noteworthy that, according to the Pilote Affidavit at paragraph 40, the MRL used for chickpeas in the CFIA Data was the MRL assigned to white beans and that no problems were identified. This means that the MRL for white beans is appropriate for chickpeas and the fact that there may be new growth on a chickpea plant at harvest which attracts glyphosate is not a significant concern.

[40] The Applicants also submit that the 1992 Study is out of date. However, the Applicants have submitted no studies which demonstrate a scientifically founded doubt about the use of white beans as the representative crop for chickpeas.

[41] The Applicants are also concerned that farmers will ignore the directions on the labels and will apply glyphosate to crops too early or when the plants are physiologically immature. However, they have not provided evidence that farmers have any motivation to apply glyphosate at an early stage in a crop's development.

[42] The study by Kristen McNaughton which the Applicants included in the NOO at page 4 under the heading "Dry Beans", observes that a farmer will not use glyphosate if the yield and quality of his or her crop will be compromised. Farmers have no incentive to apply glyphosate in a way that destroys their crops or risks residues at levels that prohibit export. In my view, the

author of the Applicants' own study negates their concerns. Further, the Applicants have not produced any evidence to show that farmers have actually applied glyphosate early to immature crops.

[43] Lastly, the PCP Act imposes penalties when a farmer fails to follow directions on labels. See sections 6(5)(b) and 6(9) of the PCP Act. However, the Applicants suggest that enforcement by the CFIA will not be effective.

[44] In my view, farmers' behaviour and enforcement issues are not topics for a panel of expert scientists.

[45] The Applicants raised six scientific studies about glyphosate in their NOO. Three studies deal with moisture but do not conclude that there is a problem when glyphosate is applied when moisture levels are below 30%. These studies are: the Cessna wheat seed study and the two Zhang lentil studies listed on page 3 of the NOO. Two of the studies, the Cessna canola study listed in the NOO on page 3, footnote 4, and the McNaughton dry beans study on page 4 of the NOO, both of which were discussed earlier in these reasons, deal with the effects of moisture and maturity but do not identify any problems with the directions for glyphosate application found on the current labels. The Cessna field pea, barley and flax seed study on page 4 of the NOO may indicate a concern with flax seed and glyphosate residues, but this concern was not raised by the Applicants, and the study does not conclude that using glyphosate on flax poses a health concern.

[46] The NOO introduces the findings of these six scientific studies by saying that:

> The scientific literature indicates that the early application of glyphosate as a desiccant or the application of glyphosate when moisture content is too high has resulted in exceedances of the Maximum Residue Limits ("**MRLs**") for some crops

> . . .
>
> In conclusion, the literature shows that MRLs for some crops, in particular cereals and legumes, can be exceeded when glyphosate is used as a desiccant and the crop has high moisture content, . . .

[47] There is no issue that if glyphosate is applied as a desiccant to immature crops or to crops with a moisture content above 30%, or in large quantities, the residue levels will be unacceptable. Accordingly, these studies do not deal with contentious issues.

[48] For this reason and given that the Response shows that the PMRA did consider these studies, it was not obliged to deal with them in detail in the Response.

[49] Dealing with the other comments on this issue, I note that the Applicants' concerns were addressed in that:

i. The Response showed that a dietary risk assessment was conducted for chickpeas; and

ii. The Response also indicated that the CFIA Data recorded the impact of desiccation on chickpeas and no health risks of concern were identified.

[50] Lastly, the NOO was critical of the PMRA for not setting an MRL for chickpeas given the dramatic increase in chickpea consumption. However, sections 9 and 10(1) of the PCP Act state that setting an MRL for crops such as chickpeas is a matter of discretion and there is no statutory obligation to do so. Further, there was no well-founded scientific evidence presented which supported a need for an MRL for chickpeas.

[51] To conclude on this issue, I am not persuaded that there were any studies which raised a scientifically well founded doubt which would justify the appointment of a review panel.

B. *Issue II – Dietary Consumption Data*

[52] The Applicants' concern was that outdated data were used. The Comment reads as follows:

> Comment 4: A comment was received which expressed concern regarding PMRA's use of CSFII – 1994-1995, 1998 Continuing Survey of food Intakes by Individuals and United States WWEIA consumption data to assess dietary risk in the re-evaluation of glyphosate. Safe Food Matters argued that a dietary risk assessment using these data is inadequate because of the evidence that current levels of consumption and production of desiccated legumes like chickpeas and lentils has increased dramatically. Accurate information showing the increase in consumption would increase the numbers for the calculations of glyphosate exposure through diet.

[53] By way of background, CSFII 1994-1996, 1998 refers to the 1998 dietary consumption data, and DEEM 2.14 refers to the 2009 software used to model this data. NHANES/WWEIA refers to the 2010 dietary consumption data, and "a new version of DEEM-FCID" refers to the 2013 modelling software for the 2010 data.

[54] The Pilote Affidavit deals with this issue at paragraph 54. There she states:

> . . . As explained in the January 11, 2019 decision letter to Ms. McDonald, the PMRA had conducted a dietary exposure analysis relating to all pesticides (not specifically glyphosate) using DEEM-FCID™ with NHANES/WWEIA for the purpose of comparing the results with the analysis under DEEM 2.14, and determined that there was consistency in the food intake pattern and no significant differences in overall dietary exposure.

[55] There are no studies mentioned in the NOO which contradict the PMRA's conclusion that the 2010 data which became available in 2013, are not materially different from the earlier data PMRA used which was from 1994-96 and 1998.

[56] There are two newspaper articles about increases in chickpea consumption which are described in footnotes 6 and 7 of the NOO and at page 8 of the NOO there is a chart prepared by Statistics Canada which shows increased pulse production. This chart is relevant because chickpeas are a pulse. However, there is no indication that there is any dietary consumption data of the sort relied on by PMRA which takes this increased consumption into account. Therefore, I cannot identify a scientifically founded doubt which would justify the appointment of a review panel.

[57] In their Memorandum of Argument, the Applicants raised for the first time a concern that the Re-Evaluation at page 4 found that the exposure estimates for children 1-2 years old met 70% of the Acceptable Daily Intake [ADI]. The Applicants submit that this is contrary to the protection demanded by the PCP Act for vulnerable groups. The Respondent said in oral submissions that the exposure estimate of 70% is not of concern because the ADI is set at a level that would pose no significant harmful effects. However, since this issue of whether 70% of the ADI is unsafe was not raised in the NOO and was not mentioned in the Pilote Affidavit or the Respondent's Memorandum of Argument, it was not properly before me and will not be considered.

C. *Issue III – The Margin of Exposure*

[58] The Response recorded the Applicants' concerns as follows:

> Comment 7: A comment was received which referenced the aggregate risk assessment in PRVD2015-01 conducted for children 1 to less than 2 years old, examining post-application dermal exposure of glyphosate and incidental oral exposure (hand-to-mouth) from performing postapplication activities in treated lawns/turf + chronic dietary (food and drinking water). This aggregate exposure scenario initially assumed a glyphosate application rate of two applications with a seven day interval. At

> that application rate, the aggregate margin of exposure for children (1 to < 2 years old) did not reach the target of 100. Therefore, refinements to the risk assessment were required.
>
> Safe Food Matters Inc. claimed that in response to this finding the 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.

[59] In this context, the Margin of Exposure (MOE) is a factor used to assess the safe exposure to glyphosate from all sources including diet, drinking water and the environment. Since 100 was determined to be the safe factor, an MOE of 100 or more was the target. An MOE below 100 indicates unsafe exposure.

[60] It is noteworthy that the PCP Act does not require the PMRA to have reliable scientific data to support a decision to reduce the number of times children are expected to be exposed to glyphosate in a given period. This means that logic and common sense can be used in appropriate circumstances to justify such a change.

[61] The results of the study of exposure in rats were modelled to extrapolate the impact on humans of all ages. In that exercise, it was assumed that two exposures would occur 7 days apart at the maximum application rate. In these circumstances, the target of 100 was not reached for children aged one to less than two years.

[62] However, the PMRA noted at page 28 of the Proposed Re-Evaluation that its assumptions had been unreasonable and that it had adjusted them because:

- they had used US MRLs for barley wheat and oats even though 99% of these crops studied were produced in Canada; and
- one application at the maximum rate made more sense than two exposures given the short 7 day timeframe.

[63] In the result, the factor of 100 was achieved for all age groups.

[64] In my view, the Applicants have not demonstrated that there is a scientifically well-founded doubt about the appropriateness of the PMRA's revision of its assumptions.

D. *Issue IV – The Safety or PCPA Factor*

[65] The Response recites the Applicants' concern as follows:

> Comment 1: A comment was received which objected to reductions of the safety factor without scientific rationale with regards to the serious endpoint of cardiovascular malformations in the rabbit developmental toxicity study. The objector indicates 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.

[66] If glyphosate is applied around homes or schools, the PCPA factor requires the PMRA to apply a margin of safety which is 10 times the margin that would otherwise apply.

[67] It is important to note that in an ordinary calculation, there are already two factors that build in caution – a factor of 10 for interspecies variability, and another factor of 10 for intraspecies variability – to a base uncertainty factor of 100. The PCPA factor adds a further safeguard to assume further uncertainty where children are concerned, i.e. a 10-fold PCPA factor would increase the overall uncertainty factor to 1000.

[68] As well, in this situation, the PMRA is required by section 19(2)(b)(iii) of the PCP Act to have a basis in reliable scientific data for changing the 10 fold standard.

[69] The PMRA relied on the fact that, in the study of glyphosate toxicity in maternal and fetal rabbits the end points were clear. This meant that the data showed a clear demarcation between doses of glyphosate which did and did not show negative health effects.

[70] The PMRA says that because there was maternal toxicity the impact of the glyphosate on the fetus could be reduced because some of the negative health effects in the fetus could be attributed to the fact that the mother's ill health itself negatively affected the fetus. This reasoning led the PMRA to reduce the safety factor from 10-3 for females ages 13-49 and from 10-1 for other populations. This means that women of child bearing age receive extra protection.

[71] The Applicants say that the PCPA factor cannot be reduced here and rely on Science Policy Note [SPN] 2008-01 at section 4.3. It reads:

> If toxicity data indicate no prenatal or postnatal toxicity or the level of concern is low (and the data is considered complete), then the presumption for use of the 10-fold PCPA factor will be obviated with respect to the potential for prenatal and postnatal toxicity (i.e. the PCPA factor would be reduced to one-fold). If the level of concern is high, the 10-fold PCPA factor will be retained.

[72] However, the PMRA says that it is entitled to reduce the factor here under the first paragraph of section 4.1 of SPN 2008-01. It reads:

> Under the new Pest Control Products Act (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 evaluation 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). 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.
>
> [Footnote omitted]

[73] In my view, the Applicants have not shown a well founded scientific doubt concerning the PMRA's decision to reduce the PCPA Factor. This issue raised concerns about the interpretation of SPN 2008-01 and whether the PMRA's interpretation was reasonable. Statutory interpretation is not the purview of a panel of expert scientists.

VIII. Overall Conclusion

[74] It is my conclusion that the Applicants have not shown in their NOO that there exists scientifically founded doubt about the validity of the Evaluations. For this reason, this application for judicial review of the Decision not to appoint a review panel will be dismissed.

JUDGMENT IN T-277-19

THIS COURT'S JUDGMENT is that

i. This application for judicial review is hereby dismissed; and

ii. Each party is to bear its own costs as a result of an agreement reached between the parties.

"Sandra J. Simpson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-277-19
STYLE OF CAUSE:	MARY LOU MCDONALD AND SAFE FOOD MATTERS INC. v ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	JANUARY 30, 2020
JUDGMENT AND REASONS:	SIMPSON J.
DATED:	FEBRUARY 13, 2020

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