Health Canada | Santé Canada
Pest Management Regulatory Agency | Agence de réglementation de la lutte antiparasitaire

Reference No. 2017-3047

September 29, 2022

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

Dear Ms. McDonald,

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

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

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

Legislative and Regulatory Framework for Decision

The risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health or future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration: subsection 2(2) of the *PCPA*. The objections submitted challenged PMRA's assessment of the health risks in relation to the re-evaluation decision for glyphosate.

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

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

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

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

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

Section 35 of the *PCPA* provides any member of the public an opportunity to file a Notice of Objection (NoO) within 60 days after the final re-evaluation decision is published. The NoO process permits PMRA to seek the assistance of an external expert review panel in response to the NoO, where warranted, and provides another opportunity for an interested member of the public to participate in the scientific aspects of the re-evaluation process. To this end, the purpose of a Notice of Objection is to identify the aspects of the scientific evaluation supporting the registration or re-evaluation/special review decision to which objection is taken and to request that the scientific aspect in question be referred to an external review panel whose role is to review the decision for the purpose of recommending whether the decision should be confirmed, reversed or varied.

The *Review Panel Regulations* ("*Regulations*") support the NoO process under the *PCPA.* Subsection 2(c) of the Regulations requires a scientific basis for the objection to the evaluations on which the decision was based. Subsection 2(d) of the *Regulations* requires that the Notice of Objection also include the evidence to support the objection, including scientific reports or test data. Since NoOs are filed after a lengthy scientific evaluation and public consultation, they should be precise in identifying the scientific aspect to which objection is taken and should be well-supported by evidence.

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

Section 3 of the *Regulations* states:

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

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

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

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

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

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

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

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

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

    a) Is there is a lack of agreement among federal government regulatory scientists with

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

respect to the evidence presented in the objection, and could it affect the outcome of the evaluation?

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

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

Summary of the Notice of Objection under Review

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

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

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

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

PMRA's Consideration of the Objections:

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

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

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

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

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

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

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

Pre-harvest use versus Desiccant use:

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

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

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

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

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

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

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

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

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

i. Was the information available prior to publishing the decision?

- **If the information was available, was it considered in the assessment?**

ii. If the evidence was not considered, does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product?

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

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

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

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

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

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

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

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

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

MRL exceedances do not equate to a health risk:

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

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

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

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

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

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

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

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

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

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

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

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

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

c) Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?

i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'

ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

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

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

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

Safe Food Matters Inc. stated that it would appear that an examination of the risks arising from dietary exposure to crops that have been desiccated with glyphosate was not part of the Re-evaluation, and maintained that such an examination is necessary, particularly given the mechanisms by which MRLs can be exceeded in desiccated crops, and that data from the CFIA indicates that exceedances are occurring.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

c) Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?

i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'

[j] Refer to footnotes g, h

ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

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

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

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

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

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

Yes, this objection is directly linked to the evaluation of the pest control product.

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

i. Was the information available prior to publishing the decision?

- **If the information was available, was it considered in the assessment?**

ii. If the evidence was not considered, does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product?

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

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

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

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

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

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

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

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

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

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

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

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

While PMRA acknowledges the increase of production and consumption of pulses since 2010, this increase is not expected to result in dietary risks of concern (i.e., risks above 100% ADI or 100% ARfD) from glyphosate exposure for the following reasons:

1) The critical commodity analysis of the dietary exposure assessment conducted for the glyphosate re-evaluation, which identifies the specific food commodities that contribute the most to the dietary exposure, showed that no food commodity from pulse crops contributed more than 1% of the total exposure for any population subgroup. However, even if pulse crop consumption increased substantially, because the current dietary exposure estimates are based on highly conservative assumptions, exposure would still be well within acceptable levels (see below).
2) As reported in the consultation document (PRVD2015-01), the dietary exposure estimates (i.e., potential daily intake for each population subgroup)) were well below the ADI, as well as the ARfD: 20 – 70% of the ADI and 12 – 45% of the ARfD for all population subgroups. Thus, a considerable portion of these reference values remains ‘available’ before any exposure concerns would be identified.

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

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

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

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

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

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

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

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

The advice of expert scientists would not assist in addressing the subject matter of this objection regarding the dietary exposure from the consumption of crops that may be treated with glyphosate, as there is agreement among federal government regulatory scientists with respect to the evidence presented in this objection. This objection was reviewed by PMRA scientists not involved in the original re-evaluation of glyphosate, who determined that the while PMRA acknowledges the increase of production and consumption of pulses since 2010, this increase is not expected to result in dietary risks of concern.

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

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

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

c) Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?

i. Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'

ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

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

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

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

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

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

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

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

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

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

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

i. **Was the information available prior to publishing the decision?**
   - **If the information was available, was it considered in the assessment?**

ii. **If the evidence was not considered, does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product?**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[s] Crop Grouping – IR-4 Project

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

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

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

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

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

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

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

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

c) **Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?**

   i. **Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'**

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

ii. Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?

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

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

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

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

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

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

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

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

i. Was the information available prior to publishing the decision?

- **If the information was available, was it considered in the assessment?**

ii. If the evidence was not considered, does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[y] Refer to footnotes g, h.

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

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

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

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

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

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

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

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

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

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

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

Yes, this objection is directly linked to the evaluation of the pest control product.

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

i. Was the information available prior to publishing the decision?
- **If the information was available, was it considered in the assessment?**

ii. If the evidence was not considered, does the information meet the criteria for scientific acceptability for use in the evaluation of a pest control product?

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

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

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

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

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

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

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

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

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

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

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

In determining whether to reduce the *PCPA* factor, PMRA considers contextual information. For example, PMRA took into account that assessing potential harm to a maternal animal will overlap with

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

c) **Is there a lack of uniformity in global regulatory evaluations related to the health or environmental risks, or value, of the pest control product that is the subject matter of the objection?**

[ee] Refer to footnotes g, h

i. **Does the lack of uniformity concern an aspect of the evaluation that is relevant to the Canadian use pattern?'**
ii. **Does the lack of uniformity relate to the scientific risk assessment or a legislative requirement in the foreign jurisdiction that is not applicable to the Canadian context?**

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

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

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

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

Sincerely,

M. E. Silva

Digitally signed by Silva, Minoli
Reason: On behalf of Frédéric Bissonnette
Location: Ottawa
Date: 2022.09.29 12:09:25-04'00'
Foxit PDF Editor Version: 11.2.1

For:
Frédéric Bissonnette
Chief Registrar
Pest Management Regulatory Agency

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