Court File No. T-2292-22

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.

Applicant

AND:

THE ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

AFFIDAVIT #1 of MARY LOU McDONALD

I, Mary Lou McDonald, a Director and Officer and General Counsel for Safe Food Matters Inc., the Applicant in this proceeding, of the Town of Gilmour, in the Province of Ontario, AFFIRM THAT:

1. I am a director and officer and general counsel for the Applicant, Safe Food Matters Inc. ("SFM"). As such I have personal knowledge of the facts set out in this affidavit, except where those facts are stated to be based upon information and belief, in which case I believe them to be true.

2. SFM is a Canadian charitable corporation founded in 2016. SFM's corporate purpose is to promote the health of Canadians by upholding the administration of laws concerning the assessment of the safety of food inputs that are protective of

human health. SFM takes the position that proper pesticide regulation is essential to the health and well-being of Canadians.

3. SFM believes that numerous formulations of agricultural herbicides based on glyphosate, including the glyphosate-based products marketed under the trade name "Roundup", are likely carcinogenic and that application of glyphosate-based herbicides in accordance with its current directions for use makes the food to which they are applied unhealthy and unsafe to eat. Glyphosate-based herbicides are the most widely used agricultural herbicide in Canada and worldwide. Roundup is marketed and distributed by the agri-pharmaceutical corporation Bayer AG, which purchased the chemical producer Monsanto in 2018. Bayer also markets and distributes crop seeds that are genetically modified to survive application of Roundup, so that Roundup kills all plants other than the seeds sold by Bayer.

4. Roundup was registered for use in Canada in 1976 and it has been continuously registered for use since then in numerous formulations for agricultural, silvicultural and commercial use. In 2005, the Pest Management Regulatory Agency ("PMRA"), which is a department of the Ministry of Health, gave approval to a label expansion that allowed glyphosate (in the "Roundup WeatherMAX" formulation) to be used as a pre-harvest desiccant on a variety of crops, including chickpeas. In 2009, the PMRA gave notice of its intention to re-evaluate glyphosate to determine whether it should remain registered for use. On April 13, 2015, the PMRA made public a proposed re-evaluation decision and engaged in a public consultation process, including with Monsanto.

5. On April 28, 2017, after completing the public consultation process, the PMRA issued a re-evaluation decision permitting the continued registration of glyphosate products for use in Canada (the "Re-evaluation Decision"). Attached as **Exhibit A** is a copy of the Re-evaluation Decision. The Re-evaluation Decision was made 41 years after the initial registration and 12 years after the re-evaluation was required by statute to be initiated.

6. On June 27, 2017, I filed a Notice of Objection to the Re-evaluation Decision on behalf of myself and on behalf of SFM (the "NoO"), requesting that the Minister of Health (the "Minister") appoint an independent science review panel under the *Review Panel Regulations* of the *Pest Control Products Act*. Attached as **Exhibit B** is a copy of the NoO.

7. On January 11, 2019, the PMRA issued its decision denying the request to appoint an independent science review panel under the *Review Panel Regulations* ("Decision #1"). Attached as **Exhibit C** is a copy of Decision #1.

8. SFM and I initiated a judicial review of Decision #1. The judicial review was dismissed by the Federal Court with reasons for judgment indexed at *McDonald v. Canada (Attorney General)*, 2020 FC 242 (CanLII). SFM initiated an appeal of the judicial review decision, which found Decision #1 to be unreasonable and ordered a reconsideration of Decision #1. The reasons for judgment of the Federal Court of Appal are indexed at *Safe Food Matters v. Canada (Attorney General)*, 2022 FCA 19 (CanLII).

9. On September 22, 2022, the PMRA issued their reconsideration decision, which again denies the request to appoint an independent science review panel under the *Review Panel Regulations* ("Decision #2"). Attached as **Exhibit D** is a copy of Decision #2.

AFFIRMED REMOTELY by Mary Lou McDonald stated as being located at the Township of Gilmour, in the Province of Ontario, before me at the City of Toronto in the Province of Ontario, on April 21, 2023, in accordance with *O. Reg 431/20*, *Administering Oath of Declaration Remotely*.

Bronwyn Roe

Commissioner for Taking Affidavits
Bronwyn Roe, LSO #63840R

M McDonald

MARY LOU McDONALD

Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Re-evaluation Decision RVD2017-01

Glyphosate

This is **Exhibit "A"** referred to in the Affidavit of Mary Lou McDonald affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely, this 21st day of April, 2023

Bronwyn Roe

Commissioner for Taking Affidavits
Bronwyn Roe, LSO #63840R

(publié aussi en français)

28 April 2017

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Executive Summary

Health Canada's primary objective in regulating pesticides is to protect Canadians' health and their environment. Pesticides must be registered by Health Canada's Pest Management Regulatory Agency (PMRA) before they can be imported, sold, or used in Canada. Pesticides must go through rigorous science-based assessments before being approved for sale in Canada.

All registered pesticides must be re-evaluated by the PMRA on a cyclical basis to make sure they continue to meet modern health and environment safety standards and continue to have value. In 2015, the PMRA published the outcome of its extensive re-examination of glyphosate for public comment (PRVD2015-01), which concluded that the products containing glyphosate do not present unacceptable risks to human health or the environment when used according to the revised product label directions.

During this re-examination, the PMRA assessed the potential human health risk of glyphosate from drinking water, food, occupational and bystander exposure, as well as the environmental risk to non-target organisms. Both the active ingredient and formulated products were included in the re-evaluation. The assessment was carried out based on available information provided by the manufacturer of the pesticide, as well as a large volume of published scientific literature, monitoring information (for example, ground water and surface water) and reviews conducted by other regulatory authorities.

The overall finding from the re-examination of glyphosate is highlighted as follows:

- Glyphosate is not genotoxic and is unlikely to pose a human cancer risk.
- Dietary (food and drinking water) exposure associated with the use of glyphosate is not expected to pose a risk of concern to human health.
- Occupational and residential risks associated with the use of glyphosate are not of concern, provided that updated label instructions are followed.
- The environmental assessment concluded that spray buffer zones are necessary to mitigate potential risks to non-target species (for example, vegetation near treated areas, aquatic invertebrates and fish) from spray drift.
- When used according to revised label directions, glyphosate products are not expected to pose risks of concern to the environment.
- All registered glyphosate uses have value for weed control in agriculture and non-agricultural land management.

All comments received during the consultation process were taken into consideration. These comments and new data/information resulted in only minor revisions to the proposed regulatory decision described in PRVD2015-01. Therefore, the PMRA is granting continued registration of products containing glyphosate with requirements of additional label updates to further protect human health and the environment.

To comply with this decision, the required label changes must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this document.

Re-evaluation Decision for Glyphosate

After a re-evaluation of the herbicide glyphosate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing glyphosate for sale and use in Canada.

An evaluation of available scientific information found that products containing glyphosate do not present risks of concern to human health or the environment when used according to the revised label directions. As a requirement for the continued registration of glyphosate uses, new risk reduction measures are required for the end-use products registered in Canada. No additional data are being requested at this time.

Findings of the re-evaluation of glyphosate were first presented for public consultation in the Proposed Re-evaluation Decision PRVD2015-01, *Glyphosate*,[1] whereas this Re-evaluation Decision (RVD2017-01)[2] summarizes the Agency's final decision on the re-evaluation of glyphosate and the reasons for it.

Comments received during the consultation period were taken into consideration. These comments and new data/information resulted in revisions to some parts of the risk assessments, however, they did not result in substantial changes to the proposed regulatory decision as described in PRVD2015-01. Appendix I of this document summarizes the comments received and provides the PMRA's response.

To comply with this decision, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this document. Registrants of the products containing glyphosate will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

Health Canada's pesticide re-evaluation program considers potential risks[3] as well as the value[4] of pesticide products to ensure they meet modern standards established to protect human health and the environment. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

In 2010, Health Canada published a re-evaluation work plan for glyphosate (REV2010-02) outlining the focus of this re-evaluation and indicating that the PMRA is working cooperatively with the United States Environmental Protection Agency. As part of this re-evaluation, the effect of Polyethoxylated Tallow Amines (POEA) and the metabolite and transformation product Aminomethylphosphonic acid (AMPA) are also included.

What Is Glyphosate?

Glyphosate is a broad-spectrum, non-selective herbicide. It controls many annual weeds, perennial weeds, woody brush and weedy trees. It is registered for use on a wide variety of sites including terrestrial feed and food crops, terrestrial non-food, non-feed and fibre crops, and for non-agricultural, industrial and residential weed management for non-food sites, forests and woodlots, outdoor ornamentals and turf.

Glyphosate is present as the free acid or as a salt in formulated end use products. Glyphosate products are formulated as solutions, pastes or tablets and can be applied using ground or aerial application equipment. Other application techniques are also used to apply glyphosate, such as with a wiper or wick applicator, cut stump or stem injection treatment. The rate of application ranges from 0.25 to 4.32 kg a.e./ha, depending on weed species (for example, annual vs. perennial) and use site. All products containing glyphosate currently registered under the authority of the *Pest Control Products Act* are listed in Appendix II.

Health Considerations

Can Approved Uses of Glyphosate Affect Human Health?

Products containing glyphosate are unlikely to affect your health when used according to label directions.

Potential exposure to glyphosate may occur through diet (food and water), or when handling and applying the product, or by entering treated sites. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Glyphosate is of low acute oral, dermal and inhalation toxicity. It is severely irritating to the eyes, non-irritating to skin and does not cause an allergic skin reaction.

Registrant-supplied short and long term (lifetime) animal toxicity tests, as well as numerous peer-reviewed studies from the published scientific literature were assessed for the potential of glyphosate to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects.

The most sensitive endpoints for risk assessment were clinical signs of toxicity, developmental effects, and changes in body weight. The young were more sensitive than the adult animals. However, the risk assessment approach ensures that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Food and Water

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Potential acute and chronic dietary exposures to glyphosate were estimated from residues of glyphosate and relevant metabolites in both treated crops and drinking water. Exposure to different subpopulations, including children and women of reproductive age, were considered. The acute dietary exposure estimate from food and drinking water at the 95th percentile represents 31% of the acute reference dose (ARfD) for females 13-49 years of age, and ranges from 12% to 45% of the ARfD for all other population subgroups. The chronic dietary exposure estimate for the general population represents 30% of the acceptable daily intake (ADI). Exposure estimates for population subgroups range from 20% of the ADI (for adults aged 50 years or older) to 70% of the ADI (for children 1-2 years old). Thus, acute and chronic dietary risks are not of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose a health risk concern.

Canadian MRLs for glyphosate are currently specified for a wide range of commodities (MRL database http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php). Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under Subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues do not exceed 0.1 ppm. Separate MRLs have been established for the trimethylsulfonium (TMS) cation, the major metabolite of the glyphosate-TMS salt, in/on a variety of commodities. Given that all glyphosate-TMS-containing products have been discontinued in Canada, all MRLs for the TMS cation will be revoked.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern when used according to label directions.

Residential exposure may occur from the application of products containing glyphosate to residential lawns, and turf (including golf courses), gardens and trees. Residential handler exposure could occur from mixing, loading and applying domestic-class glyphosate products. These products can be applied as a liquid by a manually pressurized handwand, backpack, sprinkler can and ready-to-use sprayer.

Residential postapplication exposure may occur for persons performing activities on treated areas. This includes areas treated by residential handlers as well as residential areas treated by commercial applicators. Exposure is predominantly dermal. Incidental oral exposure may also occur for children (1 to <2 years old) playing in treated areas.

For all domestic class products, the target dermal and inhalation margins of exposure (MOE) were met for adults applying glyphosate and are not of concern. Residential postapplication activities also met the target dermal MOE for all populations (including golfers) and are not of concern. For incidental oral exposure, the target oral MOEs were met for children (1 to <2 years old) and are not of concern.

Non-occupational scenarios were aggregated with background (chronic) dietary exposure (food and drinking water). The resulting aggregate risk estimates reached the target MOE for all uses and are not of concern.

Non-occupational risks from bystander dermal exposure are not of concern.

Bystander exposure may occur when the general public enter non-cropland areas (for example, hiking through forests or parks) that have recently been treated with glyphosate. The resulting risk estimates associated with bystander dermal exposure met the target MOE for all populations and are not of concern.

Occupational Risks from Handling Glyphosate

Occupational risks to handlers are not of concern when used according to label directions.

Risks to handlers are not of concern for all scenarios. Based on the precautions and directions for use on product labels reviewed for this re-evaluation, risk estimates associated with mixing, loading and applying activities met the target dermal and inhalation MOEs and are not of concern.

Postapplication risks are not of concern for all uses.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. Based on the current use pattern for agricultural scenarios reviewed for this re-evaluation, postapplication risks to workers performing activities, such as scouting, met the target dermal MOEs and are not of concern. A minimum restricted entry interval of 12 hours is required for agricultural sites.

Polyethoxylated Tallow Amines (POEA)

POEA is a family of several compounds that are used as surfactants in many glyphosate products registered in Canada. No human health risks of concern were identified for these end-use products, provided that they contain no more than 20% POEA by weight. All of the currently registered glyphosate end-use products in Canada meet this limit.

Environmental Considerations

What Happens When Glyphosate Is Introduced Into the Environment?

When used according to revised label directions, glyphosate products are not expected to pose risks of concern to the environment. Labelled risk-reduction measures mitigate potential risks posed by glyphosate formulations to non-target plants and freshwater/marine/estuarine organisms.

When glyphosate is released into the environment, it can enter soil and surface water. Glyphosate breaks down in soil and water and is not expected to remain for long periods of time. Glyphosate produces one major break down product in soil and water, aminomethyl phosphonic acid (AMPA), which can last in the environment. Carryover of glyphosate and AMPA into the next growing season is not expected to be significant. Glyphosate and AMPA are not expected to move downward through the soil and are unlikely to enter groundwater.

Glyphosate dissolves readily in water but is expected to move into sediments in aquatic environments. Glyphosate is not expected to enter the atmosphere. Glyphosate and AMPA are unlikely to accumulate in animal tissues.

Certain glyphosate formulations include a surfactant composed of POEA compounds. At high enough concentrations, POEA is toxic to aquatic organisms but is not expected to remain in the environment. While, in general, glyphosate formulations that contain POEA are more toxic to freshwater and marine/estuarine organisms than formulations that do not contain POEA, they do not pose risks of concern to the environment when used as directed on the label.

In the terrestrial environment the only risk identified was for terrestrial plants, therefore, spray buffer zones are required to reduce exposure to sensitive terrestrial plants.

Glyphosate formulations pose a negligible risk to freshwater fish and amphibians, but may pose a risk to freshwater algae, freshwater plants, marine/estuarine invertebrates and marine fish if exposed to high enough concentrations. Hazard statements and mitigation measures (spray buffer zones) are required on product labels to protect aquatic organisms.

Glyphosate, AMPA and POEA do not meet all Toxic Substances Management Policy (TSMP) Track 1 criteria and are not considered Track 1 substances. Other than incident reports of damage to plants and one exceptional incident regarding fish in a river (PRVD2015-01, Section 4.2.3), there are currently no environmental incident reports involving glyphosate in Canada.

Value Considerations

What is the Value of Glyphosate?

Glyphosate plays an important role in Canadian weed management in both agricultural production and non-agricultural land management and is the most widely used herbicide in Canada.

Glyphosate is an important herbicide for Canadian agriculture:

- Due largely to its broad and flexible use pattern and its wide weed-control spectrum, it is the most widely used herbicide in several major crops grown in Canada, such as canola, soybean, field corn and wheat. It is also one of only a few herbicides regularly used in fruit orchards, such as apple.
- It is the essential herbicide for use on glyphosate tolerant crops (GTCs), including canola, soybean, corn, sweet corn and sugar beet. The combination of GTCs and glyphosate has been adopted as an important agricultural production practice in Canada.
- It has a wide application window ranging from pre-seeding to after seeding (prior to crop emergence), in-crop, pre-harvest or post-harvest, providing a flexible and effective weed management program.
- It is one of a few herbicides that can also be used as a harvest management and desiccation treatment.
- Post-harvest stubble treatment with glyphosate allows reduced or zero tillage, which has facilitated the adoption of conservation agriculture that results in improved soil quality.

Glyphosate is also an important weed management tool and is widely used for weed control in non-agricultural land management, such as forestry, industrial areas, and along rights-of-way. It is an effective tool for control of many invasive weed species and is also used in the control of toxic plants, such as poison ivy.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of glyphosate, the PMRA is requiring further risk-reduction measures in addition to those already listed on glyphosate product labels.

Additional risk-reduction measures are discussed below. Label amendments to be implemented are found in Appendix IV.

Human Health

- To protect commercial and residential applicators: glyphosate is not to be applied using hand-wicking or hand-daubing methods.
- To protect workers entering treated sites: a restricted-entry interval (REI) of 12 hours is required for agricultural uses.
- To protect bystanders: a statement is required indicating that the product is to be applied only when the potential for drift to areas of human habitation or areas of human activity, such as houses, cottages, schools and recreational areas, is minimal.

Environment

- Environmental hazard statements are added to inform users of toxicity to non-target species.
- Spray buffer zones to protect non-target terrestrial and aquatic habitats are required.
- To reduce the potential for runoff of glyphosate to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are required. In addition, a vegetative strip between the treatment area and the edge of a water body is recommended to reduce runoff of glyphosate to aquatic areas.

What Additional Scientific Information is Being Requested?

There are no additional data requirements proposed as a condition of continued registration of glyphosate products.

International Regulatory Status and Updates on Glyphosate

The PMRA routinely works collaboratively with other member countries within the Organisation for Economic Co-operation and Development (OECD) on the regulation of pesticides. As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of a pesticide in other jurisdictions. Glyphosate is currently acceptable for use in other OECD countries, including the United States, Australia and the European Union. As of 8 March 2017, no decision by an OECD member country to prohibit all uses of glyphosate for health or environmental reasons has been identified.

In March, 2015, the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) published a summary of results of their hazard classification of five pesticides, including glyphosate. IARC classified glyphosate as probably carcinogenic to humans. It is important to note that the IARC classification is a hazard classification and not a health risk assessment. This means that the level of human exposure, which determines the actual risk, was not taken into account by IARC.

In November, 2015, the European Food Safety Authority (EFSA) finalized their re-assessment of glyphosate, concluding that glyphosate is unlikely to pose a carcinogenic hazard to humans. The EU also set an acute reference dose, which is the same as that set by the PMRA (PRVD2015-01). In May 2016, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) concluded that glyphosate is unlikely to be genotoxic at anticipated dietary exposures and that it is unlikely to pose a carcinogenic risk to humans from exposure through the diet. In March, 2017, the European Chemical Agency (ECHA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) released their determination that glyphosate is not a carcinogen. Currently, no pesticide regulatory authority, including Health Canada, considers glyphosate to be a carcinogenic risk of concern to humans.

Canada and the USEPA have been collaborating on the re-evaluation of glyphosate. In December 2016, the USEPA Scientific Advisory Panel (SAP) discussed the cancer potential of glyphosate, and Health Canada's PMRA participated as an observer. The final SAP meeting report was posted on March 17, 2017. The PMRA is continuing to monitor regulatory activities from other regulatory organizations, including the USEPA's review of the SAP recommendations and final determination regarding the potential carcinogenicity of glyphosate.

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

Other Information

Any person may file a notice of objection regarding this decision on glyphosate within 60 days from the date of publication of Re-evaluation Decision RVD2017-01, *Glyphosate*. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision), or contact the PMRA's Pest Management Information Service.

List of Abbreviations

AD	administered dose
ADI	allowable daily intake
a.e.	acid equivalent
AFC	antibody forming cells
AHS	agricultural health study
AMPA	aminomethylphosphonic acid
APVMA	Australian Pesticide and Veterinary Medicines Authority
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
ATAE	phosphate ester, tallowamine, ethoxylated
Atm	atmosphere
BAF	bioaccumulation factor
BCF	bioconcentration factor
Bt	*Bacillus thuringiensis*
BVL	The German Federal Office for Consumer Protection and Food Safety
CARC	Cancer Assessment Review Committee
CAS	Chemical Abstracts Service
CFIA	Canadian Food Inspection Agency
CHMS	Canadian Health Measures Survey
Cm	centimeter
DACO	Data Code
DAR	Draft Assessment Report
DIR	Directive
DMTT	PMRA drift mitigation technical team
DT_{50}	time required for 50% dissipation of the initial concentration
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
ECx	effective concentration on x (any number) % of the population
ECHA	European Chemicals Agency
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EDTA	Endocrine Disrupters Testing and Assessment
EFSA	European Food Safety Authority
EP	end-use product
EU	European Union
EUP	end-use product
EUP + POEA	end-use products containing the surfactant POEA
EUP NO POEA	end-use products that do not contain POEA
FA	fraction of species affected
FAO	Food and Agriculture Organization of the United Nations
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GLP	Good Laboratory Practices
GMO	genetically modified
Ha	hectare(s)

HC_5	hazardous concentration to five percent of species in a Species Sensitivity Distribution (SSD)
HD_5	hazardous dose to five percent of species in a Species Sensitivity Distribution (SSD)
Hr	hour(s)
HL	Hodgkin's lymphoma
IARC	International Agency for Research on Cancer
ICH	International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IgM	Immunoglobulin M
IPA salt	isopropylamine salt
IPCS	International Programme on Chemical Safety
IRIS	Integrated Risk Information System
JGTF	Joint Glyphosate Task Force
JMPR	Joint WHO/FAO Meeting on Pesticide Residues
K_{ow}	*n*-octanol-water partition coefficient
L	litre
Lab	laboratory
LC_{50}	lethal concentration on 50% of the population
LC_x	lethal concentration on x (any number) % of the population
Log	logarithm
LOAEL	lowest observed adverse effect level
m^3	meter cube
mg	milligram
mm	millimeter
Mn	Manganese
MOA	Mode of Action
MOE	Margin of Exposure
MRL	Maximum Residue Limit
MWCF	Molecular Weight Conversion Factor
N. bruchi	*Neochetina bruchi*
Ng	nanogram
NHL	Non-Hodgkin Lymphoma
NOAEL	no observed adverse effect level
NOEC	no-observed-effect-concentration
NOEL	no-observed-effect-level
NOI	notice of intent
NPAFC	North Pacific Anadromous Fish Commission
NTP	National Toxicology Program
NZEPA	New Zealand Environmental Protection Authority
OECD	Organization for Economic Co-operation and Development
OPP	Office of Pesticides
Pa	pascal
PCPA	Pest Control Products Act
PMRA	Pest Management Regulatory Agency
POEA	Polyethoxylated tallow amines
PPE	Personal Protective Equipment
ppm	parts per million

PRVD	Proposed Re-evaluation Decision
RAR	Renewal Assessment Report
ROS	reactive oxygen species
RD	Residue Definition
RED	Reregistration Eligibility Decision
REG	Regulatory Note
REI	Restricted-Entry Interval
REV	Re-evaluation Note
RVD	Re-evaluation Decision
SAP	Scientific Advisory Panel
SPN	Science Policy Note
spp.	species (plural)
SSD	species sensitivity distribution
Tech.	technical
TGAI	technical grade active ingredient
TSMP	toxic substances management policy
TTR	Turf Transferable Residue
UK	United Kingdom
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration
VMG	Validation Management Groups
WHO	World Health Organization

Appendix I Comments and Responses

The PMRA received written comments from the technical registrants, the public and other stakeholders relating to the *Proposed Re-evaluation Decision PRVD2015-01, Glyphosate*. The comments and PMRA responses are summarized based on common scientific themes.

1.0 Comments Related to the Health Risk Assessments

1.1 Comments Related to Toxicology

In addition to specific comments related to the toxicological evaluation of glyphosate, comments related to broader considerations, were also received. These broader comments included questions on the established paradigms for the toxicological evaluation of chemicals in general, comments on the Organization for Economic Co-operation and Development (OECD) guidelines for the testing of chemicals, concerns relating to the independence of the scientific findings, principles of Good Laboratory Practices (GLP), and other aspects of toxicological assessments. Although these broader types of comments were beyond the scope of the re-evaluation of glyphosate, every effort has been made to respond to the underlying concerns in the submitted comments as they relate to the toxicology review and health aspects of the glyphosate re-evaluation in Canada.

1.1.1 Salivary gland alterations and Acceptable Daily Intake (ADI)

Comment
The Joint Glyphosate Task Force (JGTF) proposed that the observation of cellular alterations in salivary glands results from oral irritation caused by dietary administration of glyphosate acid – a strong organic acid. New data was submitted to support this conclusion. In addition, it was noted that Canadian glyphosate formulations do not contain the technical acid, but instead contain neutral glyphosate salts (for example, potassium, ammonium, and isopropylamine). The JGTF requested that the PMRA consider the new data, re-assess the adversity of this finding, and base the ADI calculation on a more toxicologically relevant No Observed Adverse Effect Level (NOAEL).

PMRA Response
The newly submitted data consisted of a dose-range finding study and a non-guideline definitive study that examined the effects of citric acid administered to rats via gavage (to bypass direct oral exposure) or via diet, and trisodium citrate dihydrate given via diet for seven weeks. Rats treated with citric acid in their diet (a low pH diet) exhibited more pronounced changes in parotid glands (increased weight and histopathology severity) compared to rats receiving citric acid via gavage, or trisodium citrate dihydrate by diet (high pH diet).

However, an acidic diet did not appear to be the only factor responsible for changes in parotid glands, since these changes (albeit less pronounced) were also observed in both the high pH diet and gavage-treated citric acid (low pH) groups. Also, other organizations have conducted studies examining different modes of action (MOAs) that might explain changes observed in salivary glands of animals fed glyphosate-treated diets.

For example, as discussed in PRVD2015-01, (page 12), studies by the National Toxicology Program (NTP) indicated that glyphosate may be a β-adrenergic receptor agonist, as histological similarities were noted in salivary glands of animals treated with glyphosate acid, or a β-adrenergic receptor agonist (isoproterenol), and were reduced in severity by propranolol (a β-adrenergic receptor antagonist).

Additionally, the hazard assessment was based on the 'active substance' (glyphosate acid). Guideline toxicity data for "neutral" glyphosate salts, with particular attention to salivary gland examination in repeat-dose studies; were not available for selection of the toxicity endpoints.

The toxicological evaluation relied on a number of co-critical studies, rather than one 'key study', to establish each endpoint. The ADI (PRVD2015-01, page 20) is based on a 2-year study in rats with a NOAEL of 32/34 mg/kg bw/day, the highest (combined) NOAEL for all 2-year rat studies. The lowest (combined) Lowest Observed Adverse Effect Level (LOAEL) is 100 mg/kg bw/day, based on decreased body weight and increased incidences and severity of cellular alterations in the parotid and submandibular glands in one of the two-year rat studies. This choice of NOAEL and LOAEL is further supported by the NOAEL of 30 and LOAEL of 100 mg/kg bw/day, based on decreased body weight in three one-year dog studies. Thus, the selected ADI is based on two primary findings (decreased body weight as well as histological changes in the parotid salivary gland) observed in a number of different studies. No revision is required.

1.1.2 Acute Reference Dose (ARfD) for females 13-49 years of age

Comment
The endpoint selected for the ARfD for females 13-49 years of age was considered by the JGTF to be based on a spurious finding that is not reflected across developmental toxicity studies of glyphosate in rabbits. The JGTF presented an evaluation of seven rabbit developmental toxicity studies conducted by Kimmel et al. (2013), which concluded that the body of data failed to support an increased incidence of interventricular septal defects in the fetuses resulting from treatment with glyphosate during gestation in rabbits. Overall, the JGTF requested that the ARfD for this subpopulation be aligned with the ARfD for the general population.

PMRA Response
As noted in PRVD2015-01, the PMRA considered the evaluation conducted by Kimmel et al. (2013) in detail, as well as other available information, and based its conclusion on the overall weight-of-evidence in establishing an ARfD for the subpopulation of females 13-49 years of age.

Briefly, several limitations were noted in the analysis by Kimmel et al. (2013) including data tabulation errors and a lack of, or inadequately characterized, historical control data for key studies, including the study on which the PMRA based the ARfD. A re-analysis of this key study (Brooker et al. 1991, PMRA #1161779; PRVD2015-01) in conjunction with additional historical control data supplied by the JGTF resulted in the PMRA concluding that the incidence of cardiac malformations was increased relative to both concurrent and historical control data in high-dose animals, with an increase in variations at the mid-dose. The additional historical data provided by the JGTF did not alter the PMRA's original conclusions, thus, the ARfD for females 13-49 years of age was not revised.

1.1.3 Cancer Risk Assessment

Comments

1.1.3.1 International Agency for Research on Cancer (IARC) Glyphosate Monograph[5]

The majority of comments in relation to the 2015 IARC assessment, which classified glyphosate as 'probably carcinogenic to humans', requested that the PMRA review and re-assess the potential carcinogenicity of glyphosate, and restrict/ban its uses in Canada. Some comments noted that while the IARC assessment is a hazard classification, it also took into account the human exposure levels to glyphosate, largely by incorporating the epidemiological studies into the assessment. Some comments recommended that the PMRA apply the IARC classification in selecting a sensitive endpoint for occupational and bystander risk assessment in order to protect against the risk of developing non-Hodgkin's lymphoma and/or other cancers.

1.1.3.2 Ovarian Tubulostromal Tumours

The JGTF noted that PRVD2015-01 reported an increased incidence of ovarian tubulostromal tumours. The JGTF stated that these neoplasms arise out of the germinal epithelium of the ovarian stroma, are similar to those seen in epithelial hyperplasia, and therefore, do not provide sufficient evidence for oncogenicity. They also provided historical control data relevant to the strain of mice used, and noted that the reported incidence was within the range of Charles River historical control data for this finding. The JGTF requested that PMRA consider this finding as not related to glyphosate treatment and revise the text on page 89 of PRVD2015-01 from "equivocal evidence of oncogenicity" to "no evidence of oncogenicity"

1.1.3.3 Agricultural Health Study and Multiple Myeloma

The JGTF requested that the PMRA reconsider the suggested association between multiple myeloma and glyphosate use that was reported by the Agricultural Health Study (AHS) publication (De Roos et al. 2005, PMRA#:2391583). The comments indicated that it has been over 10 years since the study was conducted and a follow-up study, noted by De Roos as being necessary, has not been performed. The JGTF also noted that in an effort to understand how the conclusion of 'suggested association' was reached in the AHS study, the data were analyzed by a third-party expert (Sorahan, 2015) who determined that De Roos et. al., 2005 had pared down the AHS data set to come to the conclusion of 'suggested association'. When the full data set is analyzed, the risk ratio is 1.1, demonstrating no association between multiple myeloma and glyphosate use. Additionally, no association between multiple myeloma and glyphosate use was noted by the IARC review of glyphosate, which considered the Sorahan (2015) paper.

[5] IARC (International Agency for Research on Cancer). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 112 (2015). Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos. Available online from http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf [last accessed June, 2016]

PMRA Response to Comments 1.1.3.1 – 1.1.3.3

Background

In March, 2015, the International Agency for Research on Cancer (IARC) published a summary of the basis for their hazard classifications of five pesticides, including glyphosate, which they classified as 'probably carcinogenic to humans'. The PMRA's position on the IARC's hazard-based classification was included in PRVD2015-01, published in April, 2015, however, the full IARC monograph only became available in July, 2015. The PMRA has since reviewed this document; a summary of the PMRA review is discussed below.

The IARC Assessment

The PMRA and IARC assessments of the carcinogenic potential of glyphosate were based on different datasets and considerations. As noted in Re-evaluation Note 2010 (REV2010-02), the PMRA collaborated with the United States Environmental Protection Agency (USEPA) on the re-evaluation of glyphosate, which included the examination of published scientific toxicity data according to the principles set out in USEPA guidance.[6] Additionally, considerations laid out in a second USEPA guidance[7] document were applied in the review of published epidemiology data.

The carcinogenic potential of glyphosate acid, the technical active ingredient, was assessed by the PMRA using a weight-of-evidence approach. Many registrant-supplied studies are available on the carcinogenic potential of glyphosate, which include lifetime cancer bioassays, as well as in vitro and in vivo mutagenicity studies. In addition, published data as well as epidemiological data were available for consideration. Results were then integrated and weighed according to their reliability, relevance and consistency. Note that studies conducted with glyphosate alone were considered more relevant in characterizing its inherent toxicity than were studies on the formulated products reported in the scientific literature, as the latter contained a variety of other constituents that, in most cases, were not identified. The compositions of formulated products are considered proprietary data, and often differ between countries. However, the composition of the formulated products must be disclosed to regulatory authorities in the country of registration; (see Genotoxicity section below). Although it is argued that formulated glyphosate products are more representative of 'real life' conditions, it is important to keep in mind that many different products (pesticide and non-pesticide) share many of these same constituents. In order to fully characterize a pesticide active ingredient, it is necessary to understand its inherent toxicity, which can only be characterized in the absence of these other constituents.

6 EPA (U.S. Environmental Protection Agency), 2012, Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment. Available online from http://www2.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf [last accessed February, 2016]

7 EPA (U.S. Environmental Protection Agency), 2010, February 2010 FIFRA SAP meeting minutes: Draft Framework and Case studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment. Available online from https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0125-0079 [last accessed February 2016]

In addition, studies that complied with internationally accepted test guidelines were considered by the PMRA to be more relevant and reliable than published studies conducted with methodologies not recognized by regulatory agencies or organizations, such as the OECD. In total, the PMRA, in cooperation with the USEPA, assessed a much larger and more relevant body of scientific information than was considered by the IARC.

Conversely, in its evaluation of the carcinogenic potential of glyphosate, the IARC considered only published sources of toxicology data, which included the scientific literature and certain documents published by regulatory agencies. The IARC did not directly consider, or did not consider at all, unpublished toxicology studies that were available to international regulatory agencies. It is the PMRA's understanding that unpublished registrant-sponsored studies are not requested by the IARC for their deliberations. Furthermore, the IARC classifications of carcinogenic hazard are based on scientific consensus related to the evidence examined, but do not provide risk information or recommendations for regulation or legislation. The IARC assessment relied on many studies that did not characterize the composition of the tested mixtures (formulated products) and/or grouped all glyphosate formulated products, regardless of their composition. The composition of glyphosate formulated products differs around the world, even in those marketed under the same trade name. This difference in the evaluation approach used by the IARC and the PMRA is an important distinction because some studies, mostly in vitro, with glyphosate formulated products suggest that certain formulations are genotoxic, while studies examining the active substance alone do not show this effect. This may indicate that genotoxicity observed in these studies is related to other constituents in the formulated product rather than glyphosate acid. The constituents of all pest control products registered in Canada are disclosed to the PMRA, and toxicity data (as well as other data) are also required for each formulated product, which are examined during the pre-market review process.

Genotoxicity

The PMRA did not identify any genotoxic potential for the active ingredient glyphosate acid. Negative results for in vitro and in vivo gene mutation and chromosomal effect assays in mammalian cells contributed to the overall conclusion that the active ingredient glyphosate was not genotoxic. In vitro studies are generally conducted to predict a potential effect in animal (in vivo) studies. In vivo studies are weighted more than in vitro studies based on relevancy and integrated metabolism of the whole animal.

A large battery of genotoxicity assays conducted according to the OECD test guidelines for glyphosate is available. Many studies have been replicated several times, and all indicated negative results for genotoxicity. The IARC assessment did not consider the majority of these studies. Instead, the IARC monograph reported mixed results for studies with glyphosate formulated products that examined DNA damage, gene mutation, and chromosomal aberrations, and included results from non-mammalian systems – for example fish, and plants, that are not considered relevant for human health hazard characterization.

The IARC monograph also noted that in several cases, positive results occurred at very high or toxic dose levels only. It is important to characterize the relationship of genotoxic results in the context of observed cytotoxicity. Positive results at very high or toxic dose levels indicate that the genotoxic effects are due to cytotoxicity rather than direct DNA-acting properties of glyphosate formulated products. High-dose cytotoxicity was one factor in the weight-of-evidence

approach used by the PMRA when considering the genotoxic potential of glyphosate, and is consistent with international approaches (EFSA 2011,[8] USEPA 1986,[9] USFDA, ICH S2(R1)[10]). The observed cytotoxicity is likely associated with surfactants that are present in many formulated products. For example, polyethoxylated tallow amines (POEAs), which are typical surfactant components of many glyphosate products, were shown to produce cytotoxic effects such as perturbation/disruption of the mitochondrial membrane in cultured mammalian cells (Levine et al. 2007,[11] Kier and Kirkland 2013[12]). A number of negative genotoxicity studies were reported by Kier and Kirkland (2013), but not considered by the IARC. It should be noted that genotoxic effects resulting from cytotoxicity exhibit a threshold, and carefully selected reference doses protect against this effect.

The IARC suggested other 'mechanisms of action' that might contribute to potential carcinogenicity, such as inflammation, immunosuppression, endocrine disrupting activity and oxidative stress, which were based mainly on in vitro studies. However, no evidence of glyphosate-induced immunosuppression was observed in a registrant-supplied guideline immunotoxicity study reviewed by the PMRA. In addition, no other studies in the extensive toxicity database suggested a concern for immunotoxicity, inflammation or oxidative stress. Glyphosate also showed no evidence of interaction with estrogen, androgen or thyroid endocrine pathways in studies conducted by the USEPA Endocrine Disruptor Screening Program (EDSP).

Carcinogenicity

1. Studies in Animals

As reported in PRVD2015-01, the PMRA also assessed the carcinogenic potential of glyphosate in several long-term animal studies, which included two mouse studies and four rat studies, as well as studies in the published literature. Although, not all available carcinogenicity studies on glyphosate were submitted to the PMRA, reviews, evaluation reports, and committee meeting documents from international regulatory authorities (EFSA and USEPA) for these particular studies were considered by the PMRA. No evidence of carcinogenicity was identified in any of the rat studies reviewed by the PMRA, or in the additional rat studies reviewed by other regulatory authorities.

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8 EFSA (European Food Safety Authority), 2011. Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Scientific Committee, EFSA journal, 9, 2379

9 EPA (U.S. Environmental Protection Agency), 1986. Guidelines for mutagenicity risk assessment. Fed. Register 51. 34006-34012.

10 FDA (U.S. Food and Drug Administration), 2012. Guidance for Industry. S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use. Available online from http://www.fda.gov/downloads/Drugs/Guidances/ucm074931.pdf [last accessed February, 2016]

11 Levine SL, Han Z, Liu J, et al. (2007). Disrupting mitochondrial function with surfactants inhibits MA-10 Leydig cell steroidogenesis. Cell Biology and Toxicology, 23, 385–400. Available online from http://link.springer.com/article/10.1007%2Fs10565-007-9001-6 [last accessed June, 2016]

12 Larry D. Kier & David J. Kirkland (2013) Review of genotoxicity studies of glyphosate and glyphosate-based formulations, Critical Reviews in Toxicology, 43:4, 283-315. Available online from http://www.tandfonline.com/doi/full/10.3109/10408444.2013.770820#.V2G7ZtJIiUk [last accessed June, 2016]

The IARC assessed seven long term studies in rats and two studies in mice. Pancreatic islet cell adenomas were noted in male rats in two of the rat studies. However, these findings were not dose-related and/or occurred at the low dose only. The IARC also reported a statistically significant positive trend for hepatocellular adenomas in male rats only (with no evidence of pre-neoplastic lesions or progression to carcinomas), and a statistically significant positive trend for thyroid C-cell adenomas in female rats only. None of these tumours were reproduced in other chronic studies in rats.

PRVD2015-01 reported a marginal increase in the incidence of ovarian tubulostromal hyperplasia and adenomas in mice. However, since adenomas were observed at the limit dose of testing, they were not considered relevant for human health risk assessment. Furthermore, additional historical control data submitted during the PRVD comment period indicated that the incidence of ovarian adenomas was actually within the historical control range for the conducting laboratory, which increased the likelihood that these tumours were not treatment-related.

For the two mouse studies, the IARC identified a positive trend for renal tubule adenomas and carcinomas in male mice in one study, and a positive trend for hemangiosarcoma in males in the other study. However, these tumours were not reproduced in other mouse studies, which used similar and higher doses (1000-4000 mg/kg bw/day).

Since the publication of PRVD2015-01, a review by Greim et al. (2015[13]) of 14 long-term glyphosate toxicity/carcinogenicity studies in rodents included four additional studies in rats and three additional studies in mice, which were negative for carcinogenicity. These seven studies were not considered acceptable by the IARC due to insufficient reporting of the study methods and results by Greim et al. The PMRA had access to detailed information for these studies, which were considered acceptable for hazard characterization; and the USEPA and EFSA also considered these studies as part of their assessment of the carcinogenic potential of glyphosate.

2. Epidemiological Studies

The PMRA, USEPA and the European Food Safety Authority (EFSA[14]) have concluded that the currently available epidemiological database does not support a causal relationship between exposure to glyphosate and cancer outcomes.

A general discussion of pivotal epidemiology studies, as identified in the IARC assessment, is presented below.

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13 Helmut Greim, David Saltmiras, Volker Mostert & Christian Strupp, (2015), Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies, Critical Reviews in Toxicology, 45:3, 185-208. Available online from http://dx.doi.org/10.3109/10408444.2014.1003423 [last accessed June, 2016]

14 Ntzani EE, Chondrogiorgi M, Ntritsos G, Evangelou E, Tzoulaki I. Literature review on epidemiological studies linking exposure to pesticides and health effects. EFSA (European Food Safety Authority), EFSA supporting publication 2013:EN-497, 159 pp. Available online from http://www.efsa.europa.eu/en/supporting/pub/497e [Last accessed February, 2016]

Multiple Myeloma

As a part of a larger study known as the Agricultural Health Study (AHS), a prospective cohort study examined cancer incidence in pesticide applicators in Iowa and North Carolina. As described in PRVD2015-01, the most relevant finding in this study was a non-statistically significant association between multiple myeloma and glyphosate exposure. The relative risk was 1.1 when adjusted for age (95% CI, 0.5-2.4; 32 cases; only 20 cases reported exposure to glyphosate), but was 2.6 (95% CI, 0.7-9.4) when adjusted for multiple confounders (age, smoking, other pesticides, alcohol consumption, family history of cancer, and education). Evidence for an exposure-response trend by duration or intensity of pesticide use was not observed during the relatively short period (enrollment in the study was 1993-1997 to end of 2001) of follow-up (PMRA#:2391583). In a follow-up analysis of male participants in the same cohort, no correlation was observed between exposure to glyphosate and risk of a pre-malignant plasma disorder (monoclonal gammopathy of undetermined significance) that typically precedes the development of multiple myeloma (Landgren et al., 2009). In multiple re-analyses of the AHS data, including that of Sorahan (2015), no definitive association between glyphosate exposure and multiple myeloma was observed.

Non-Hodgkin lymphoma (NHL)

In many case-control studies, as reported by IARC, the USEPA and EFSA, some investigators observed a positive, but generally non-statistically significantly association between glyphosate use and NHL cases, while others reported no association. Variation in the quality of exposure assessment, study design and methods, in addition to a lack of available information on confounding variables may explain inconsistencies in the data. NHL is also not a specific disease, as mentioned by most authors of these studies, but consists of multiple types of lymphoma that are classified for convenience as not being Hodgkin's lymphoma. For example, multiple myeloma can also be considered a type of NHL; however, the data on multiple myeloma was analysed separately by the IARC, instead of considering it with NHL studies. The World Health Organization has dismissed the dichotomous classification of lymphomas as NHL/HL (Hodgkin's lymphoma); and 43 different types of lymphomas have been characterized (Berry 2010[15]). Proper classification of the disease (for example, the type of cancer) is important in epidemiology studies in order to adequately link it with the exposure to a chemical.

The interpretation of available epidemiological studies involving glyphosate is problematic due to a lack of adequate characterization of glyphosate exposures, the small number of cancer cases, and other confounding variables. For example, glyphosate exposure was analyzed with several other pesticides, exposure was generally based on questionnaires, classification of the type of cancer was not consistent, and the contribution of toxicity from formulants could not be assessed.

[15] Berry, C.L. 2010. Relativism, regulation and the dangers of indifferent science. The Sir Roy Cameron lecture of the Royal College of Pathologists. Toxicology 267 (2010) 7-13. Available online from http://www.sciencedirect.com/science/article/pii/S0300483X09005812?np=y [Last accessed February 2016]

Only once an association is plausibly established can criteria, (such as Bradford Hill) be considered to determine whether a causal relationship exists[16]. Without a causal relationship, epidemiology data cannot be used to establish references doses or occupational endpoints.

Finally, it is important to note that the experts convened by the IARC to assess the carcinogenic hazard of glyphosate concluded that there is limited evidence of glyphosate-related carcinogenicity in humans based on the available epidemiological studies. This conclusion is consistent with the limited utility of epidemiology studies in selecting reference doses to conduct a human health risk assessment for glyphosate.

While epidemiology data have inherent limitations, reported findings have the advantage of being directly based on human exposures and population responses. Because of these advantages, epidemiological studies may provide valuable information in the Adverse Outcome Pathway framework[17]. The PMRA continues to support the conduct of well-designed epidemiological studies where exposure conditions are well characterized.

Conclusion

Overall, the IARC concluded that the evidence of carcinogenicity was limited in humans but sufficient in animals. This conclusion was reached based on statistically increased incidences of tumour findings in four chronic studies in rodents (two in rats and two in mice), as well results from genotoxicity (mostly in vitro) assays using formulated products. However, the IARC did not reflect the lack of dose-response relationships or other contextual information (for example, background/ historical control data, cytotoxicity) in their decision.

Based on a weight-of-evidence analysis that utilized all available carcinogenicity studies in animals, together with other contextual information, the PMRA did not consider any of the observed tumours to be treatment-related. The main aspects of this weight-of-evidence analysis are highlighted below:

- A clear dose-response was not observed for any of the noted tumours
- The statistically significant findings via pairwise comparisons were weighed against the lack of dose-response relationships.
- The statistically significant positive trend was weighed against the lack of consistency across several relevant studies from a total of fourteen long term toxicity/carcinogenicity studies in rodents.
- Slightly increased tumour incidences at dose levels at or above the limit dose of testing (1000 mg/kg bw/day) were not considered relevant for human health risk assessment.

16 EPA (U.S. Environmental Protection Agency), 2010, February 2010 FIFRA SAP meeting minutes: Draft Framework and Case studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment. Available online from https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0125-0079 [last accessed February, 2016]

17 OECD, Organisation for Economic Co-operation and Development (OECD), 2012, Adverse Outcome Pathways, Molecular Screening and Toxicogenomincs. Available online from http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm [Last accessed February, 2016]

- Incidences fell within valid historical control data from the respective performing laboratories.
- There was a lack of pre-neoplastic lesions (for example, foci, hypertrophy, and hyperplasia) and/or other biologically plausible evidence (for example, mode of action data) to relate the noted tumours to glyphosate treatment.
- The weight-of-evidence from a wide range of assays, both in vitro and in vivo, that examined various endpoints such as gene mutation, chromosomal damage, DNA damage and repair, indicated no genotoxic concern for glyphosate.
- The currently available epidemiology evidence does not support a causal relationship between exposure to glyphosate and cancer outcomes.

The PMRA's determination on the carcinogenic potential of glyphosate is consistent with the most recent conclusions of other international regulatory authorities and intergovernmental organizations (USEPA CARC Report,[18] EFSA,[19] JMPR,[20] ECHA,[21] and NZEPA[22]), which concluded that glyphosate is unlikely to be genotoxic or carcinogenic. Therefore, the PMRA's conclusion with respect to the carcinogenicity of glyphosate acid, as outlined in PRVD2015-01, is unchanged.

1.1.4 Immunotoxicity

Comment

The JGTF noted that no statistically significant increase in T-cell dependent antibody response or total activity in the immunotoxicity study was observed. The JGTF requested that the statement regarding "evidence of immunotoxicity" be corrected to "no evidence of immunotoxicity." The JGTF also requested that additional wording be included to qualify PMRA's conclusion of "an altered function of the immune system could not be ruled out" to provide further context to PRVD2015-01.

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18 EPA (U.S Environmental Protection Agency), 2015, Cancer Assessment Document – Evaluation of the Carcinogenic Potential of Glyphosate. Final Report. Cancer Assessment Review Committee. Available online from http://src.bna.com/eAi [Last accessed June, 2016]

19 EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015; 13(11):4302 [107 pp.] Available online from: https://www.efsa.europa.eu/en/efsajournal/pub/4302 [Last accessed June, 2016]

20 Pesticides Residues in Food, 2016. Special Session of the Joint FAO/WHO Meeting on Pesticide Residues – Report 2016. ISSN 2070-2515. FAO Plant Production and Protection Paper 227. Available online from http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/ [last accessed June, 2016]

21 ECHA (European Chemicals Agency). Public consultation on the harmonised classification and labelling proposal for Glyphosate. ECHA/NI/16/25. 2016. Available online from http://echa.europa.eu/view-article/-/journal_content/title/public-consultation-on-the-harmonised-classification-and-labelling-proposal-for-glyphosate [last accessed June, 2016]

22 NZEPA (New Zealand Environmental Protection Authority). Review of the Evidence Relating to Glyphosate and Carcinogenicity. 2016. Available online from http://www.epa.govt.nz/Publications/EPA_glyphosate_review.pdf [last accessed August, 2016]

PMRA Response

In the registrant-submitted immunotoxicity study, a dose-related increase in the T-cell dependent antibody response (IgM (Immunoglobulin M) AFC (Antibody Forming Cells)/10^6 spleen cells) was observed. The magnitude of increase was 10%, 18%, and 31% at 150, 449 and 1448 mg/kg bw/day, respectively, compared to the control group. The test guideline stated that a response of 800-1,000 IgM AFC/10^6 spleen cells should be noted in the negative control mice for the strain used in the AFC assay. Examination of individual animal data for T-cell dependent antibody response revealed that seven, six and eight animals in low, mid- and high dose groups, respectively, had a response higher than 1000 IgM AFC/10^6 spleen cells, compared to four animals in the control group, which indicated a treatment-related effect.

PRVD2015-01 also noted a dose-related increase in total spleen activity (IgM AFC/spleen x 10^3). The magnitude of increase for this effect was 13%, 50% and 54% @ 150, 449 and 1448 mg/kg bw/day, respectively, compared to the value of the vehicle control group. A non-dose-related increase in spleen cellularity (spleen cells × 10^7) of 20% and 10% in the mid- and high dose animals, respectively was noted. This increased immune response in the AFC assay was considered potentially treatment-related. However, immune effects were not observed in the rest of the toxicity database, and ultimately, this finding did not impact the risk assessment.

In summary, the PMRA examined trends (for example, dose-response relationships) as well as statistical significance in assessing the relevance of the above findings. Given that the variation (standard deviation) in the AFC assay data are generally large, key considerations other than statistical significance were important in developing an overall conclusion. The WHO (2012[23]) recommends considering unintended immune system stimulation as a noteworthy finding, but one that may be difficult to characterize or unambiguously define as adverse. Similarly, the USFDA (2002[24]) considers unintentional immunostimulation as a potentially adverse effect.

1.1.5 Aggregate Endpoint

Comment

A number of comments contested the endpoint selected by the PMRA for aggregate risk assessment, indicating that the NOAEL of 32/34 mg/kg bw/day from a 2-year rat study was inappropriate. The comments recommended that the endpoint be based on a NOAEL of 10 mg/kg bw/day due to an increased incidence of renal tubular dilation in F_{3b} offspring at the LOAEL in a three-generation reproduction toxicity study, as identified by the USEPA Integrated Risk Information System (IRIS).

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23 WHO (World Health Organization – International Programme on Chemical Safety), 2012. Guidance for Immunotoxicity Risk Assessment for Chemicals. Available online from http://www.inchem.org/documents/harmproj/harmproj/harmproj10.pdf [Last accessed June, 2016]

24 FDA (U.S Food and Drug Administration), 2012, Guidance for Industry – Immunotoxicology Evaluation of Investigational New Drugs. Available online from http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079239.pdf [last accessed June, 2016]

PMRA Response

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation). An initial step in performing an aggregate risk assessment is to review all available toxicity data and to identify the most appropriate toxicological endpoints of concern and their associated parameters (such as dose, duration, and route).[25]

Since histological changes in the salivary glands were observed in many repeat-dose oral studies over various durations in two species (rats and mice), it was considered a common endpoint of concern for aggregate risk assessment (as indicated in PRVD2015-01, page 27), particularly for potential aggregate exposure from food, drinking water and residential scenarios. In addition, this was considered appropriate for all durations since the same effects were observed from very short term dosing (28-day) or chronic dosing (two-year) studies. In reconciling the dosing routes, it was indicated that dermal toxicity studies did not examine salivary glands histologically and repeat dose inhalation studies were not available. As such, effects on salivary glands are assumed to occur via inhalation or dermal routes in the absence of route-specific and convincing mode of action data to support route-specificity of these findings.

Furthermore, the reproduction study in which renal tubular dilation was noted in the F_{3b} offspring, was not considered acceptable due to many reporting limitations. It is also important to note that this finding was observed macroscopically in a few animals only, and was considered a spurious finding in the USEPA Office of Pesticides (OPP), JMPR and EFSA assessments. Additionally, this finding does not meet the criteria for determining an appropriate toxicology endpoint for aggregate risk assessment (SPN2003-04[26]). Therefore, the endpoint chosen for aggregate risk assessment in PRVD2015-01 remains unchanged.

1.1.6 Cumulative Risk Assessment

Comment

A number of submitted comments recommended that PMRA conduct an assessment of the cumulative effects of the glyphosate pest control product and other pest control products that have a common mechanism of toxicity.

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25 PMRA (Pest Management Regulatory Agency), 2003, General Principles for Performing Aggregate Exposure and Risk Assessments. Available online from http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2003-04-eng.pdf [Last accessed February, 2016]

26 EPA (U.S. Environmental Protection Agency), 2001, General Principles for Performing Aggregate Exposure and Risk Assessments. Available online from http://www2.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf [Last accessed February, 2016]

PMRA Response

The *Pest Control Products Act* requires that PMRA assess the cumulative effects of pesticides. A cumulative assessment evaluates the potential adverse health effects from being exposed to more than one pesticide at a time from the same pesticide "group". These groups are created based on a common toxic effect that occurs by the same or similar mechanism. Glyphosate acid does not appear to share a common mode of toxicity with other pesticides. As such it does not belong to a 'pesticide group' that requires assessment of cumulative effects.

For more information and/or a description of the steps taken to determine a pesticide "group" for assessment of cumulative effects, refer to SPN2001-01.[27]

1.1.7 The *Pest Control Products Act* (PCPA) Hazard Characterization

Comment

A number of comments recommended that the PMRA apply a 10-fold *Pest Control Products Act* factor for human health risk assessment, as required under the *Pest Control Products Act*. The comments indicated that there was evidence of sensitivity of infants and children to glyphosate in the studies discussed in PRVD2015-01. In two of the three reproduction toxicity studies, decreased body weight in rat pups was noted at non-maternally toxic doses. The PMRA was also referred to studies in the published literature that reported endocrine effects and toxicity in the young.

PMRA Response

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential pre- and postnatal toxicity.

As indicated in PRVD2015-01 (page 17) with respect to the completeness of the toxicity database of glyphosate, many available guideline and non-guideline studies have investigated the potential developmental, reproductive, and endocrine effects of glyphosate. Recently, the USEPA completed an assessment of the results of their Endocrine Disrupting Screening Program (EDSP) Tier I testing and concluded that glyphosate showed no evidence of interaction with estrogen, androgen or thyroid endocrine pathways (USEPA, 2015). It is important to note that studies required in the EDSP program are of higher quality and reliability than certain studies available in the published scientific literature, including the in vitro assays cited in the comments received on PRVD2015-01.

With respect to potential pre- and postnatal toxicity, the two-generation reproduction toxicity studies in rats provided no indication of increased sensitivity of the young. In these studies, although offspring toxicity typically consisted of decreased body weight at doses that did not

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27 PMRA (Pest Management Regulatory Agency), 2001, Science Policy Notice (SPN2001-01) Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment Available online from http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2001-01-eng.pdf [Last accessed June 2016]

appear to produce maternal toxicity, it was noted that these same dose levels produced toxicity in adult animals in other studies available in the glyphosate database, (PRVD2015-01, pages 14, 17, 80, 81) lessening the level of concern for this finding. Additionally, the selected reference doses provide a sufficient margin (1000-fold) to the dose levels at which the pup bodyweights were affected.

In summary, based on the completeness of the database with respect to developmental and reproductive toxicity, the10-fold *Pest Control Products Act* factor was reduced to 1-fold for most populations. However, a 3-fold *Pest Control Products Act* factor was retained for the ARfD for females 13-49 years of age, for reasons discussed in PRVD2015-01 (page 17) and Section 1.1.2 of this document. For more information on the application of the *Pest Control Products Act* factor, please refer to SPN2008-01.[28]

1.1.8 General Comments on Health Effects and Toxicology Review

Comment
A number of comments from various stakeholder organizations (for example, Canadian Association of Agri-Retailers, the Canola Council of Canada, and Central Kootenay Invasive Species Society) acknowledged and supported the proposed re-evaluation decision on the health aspects of glyphosate. These comments emphasized the importance of a science-based approach in reviewing glyphosate and agreed with the proposed regulatory label changes.

PMRA Response

The PMRA re-evaluation drew upon a large, comprehensive body of scientific information that included data from registrants, published scientific studies, as well as information from other regulatory authorities, which formed the basis of its conclusions.

1.1.9 Glyphosate, GMOs (Genetically modified) and Health effects

Comment
A number of comments cited information from various non-governmental organizations or independent researchers, and requested that the PMRA use these sources of information as evidence for health risks of pest control products containing glyphosate in order to restrict or phase-out the uses of these products in Canada.

[28] 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 June, 2016]

PMRA Response

As noted in previous responses, the PMRA conducted a weight-of-evidence assessment that considered all relevant, hazard/toxicity data for glyphosate, including data from registrants, published scientific studies, and information from other regulatory authorities. In the PMRA assessment, published scientific toxicity data was evaluated according to the principles set out in a published USEPA guidance document.[29]

In contrast, while the documents/websites cited in these comments attempted to consolidate a wide range of sources of information, some of these studies were of low quality and reliability due to significant reporting limitations, and/or did not utilize accepted study methodologies, while others were anecdotal in nature. Also, as discussed in response to comments 1.1.3.1-1.1.3.3, studies based on formulated products are considered less relevant to characterizing the potential inherent toxicity of glyphosate itself, due to multiple and often unidentified constituents. Thus, the submitted citations did not result in a change to the toxicity assessment for glyphosate. The studies cited in these comments that were considered by the PMRA are listed in the reference list section of this document.

1.1.10 Glyphosate and Modern Diseases (such as Autism, and Celiac Disease)

Comment

A number of comments cited published articles that link glyphosate to various health problems such as autism, and celiac disease (for example, Samsel and Seneff 2013[30]; 2015[31]), and requested that PMRA restrict and/or phase-out the uses of pest control products containing glyphosate based on health effects reported in these articles.

PMRA Response

Correlations do not provide sufficient evidence of causation. These articles report disease frequencies in specific regions over several time periods. Although correlations were reported, these were difficult to interpret, as it could not be determined whether the health outcomes preceded or followed glyphosate application. These articles also lacked sufficient detail regarding the strength, consistency and specificity of the noted correlations. For example, in regions where glyphosate applications were low, it was not clear if the health outcomes occurred at lower incidences compared to those of the regions where glyphosate applications were at higher levels. Overall, due to the lack of adequate information regarding the amount, route or duration of exposure; or the timing between exposure and the onset of the symptoms, an association and/or causality relationship could not be assessed.

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29 EPA (U.S. Environmental Protection Agency), 2012, Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment. Available online from http://www2.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf [last accessed February, 2016]

30 Samsel A, and Seneff S. 2013. Glyphosate's suppression of Cytochrome P450 enzymes and amino acid biosynthesis by the gut microbiome: pathways to modern diseases. Entropy. 15: 1416-1463.

31 Samsel A, and Seneff S. 2015. Glyphosate, pathways to modern diseases III: Manganese, neurological diseases, and associated pathologies. Surgical Neurology International. 6 (45).

1.1.11 Health Effects on the Gastrointestinal Tract and its Microbiome

Comment

A number of comments cited published articles that report an impact of glyphosate on the human intestinal microbiome, producing gastrointestinal effects which, some propose, may ultimately affect human health. Some comments noted that glyphosate is patented as an antibiotic, and requested information on the long term effects of ingesting glyphosate, on the human gut microbiome. Overall, the comments claimed that the PMRA did not address the implications of the chelation activity and antimicrobial properties of glyphosate.

PMRA Response

Glyphosate targets an amino acid synthesis pathway in plants that is shared by certain types of bacteria, but not humans. There is very little scientific evidence to support the claim that glyphosate has any direct impact on human gut microflora, or has any subsequent health effect. Several reports[32] [33] postulate that environmental chemicals may potentially lead to changes in normal gut microbiota. However, information to date is based on in vitro studies, with in vivo evidence being very limited and inconclusive.

The reference doses established by the PMRA, and documented in PRVD2015-01, include consideration of clinical signs of toxicity on the gastrointestinal tract and are considered protective of potential effects on the gastrointestinal tract.

1.1.12 Endocrine Effects

Comment

A few comments referred the PMRA to articles that indicated glyphosate was an endocrine disruptor and requested that the PMRA use this evidence to phase-out pest control products containing glyphosate.

PMRA Response

The cited articles were generally studies that examined the effects of glyphosate formulations on a specific biochemical pathway in in vitro tests. These studies frequently did not provide test material composition.

The PMRA considered multiple lines of evidence from various toxicity studies in assessing the potential for glyphosate to affect endocrine systems. Studies conducted by the NTP, guideline two-generation reproduction toxicity studies, as well as studies conducted under the US EDSP

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[32] Shehata AA, Shrödl W, Aldin AA, Hafez HM, Kürger M. 2013. The effect of glyphosate on potential pathogens and beneficial members of poultry microbiota in vitro. Current Microbiology 66(4): 350-358. Available online from http://link.springer.com/article/10.1007%2Fs00284-012-0277-2 [Last accessed June, 2016]

[33] Dietert, RR. The Microbiome in early life: self-completion and microbiota protection as health priorities. Birth Defects Research (Part B) 101: 333-340 (2014). Available online from http://onlinelibrary.wiley.com/doi/10.1002/bdrb.21116/abstract [last accessed June, 2016]

program (United States Endocrine Disruptor Screening Program), were considered. Glyphosate has not been shown to interact with any specific endocrine pathway and has no physical / chemical properties or structural similarity to other chemicals that are known to interact with the endocrine system. Finally, as noted in response to comment 1.7, the USEPA completed a weight-of-evidence assessment on results obtained from the EDSP assays and concluded that glyphosate does not interact with estrogen, androgen, or thyroid pathways and that additional Tier 2 data was not triggered.

Thus, there is no compelling evidence to suggest that glyphosate has any significant adverse effect on endocrine-related pathways. See also response to comment 2.2.7.

1.1.13 Bioaccumulation

Comment

A few comments questioned whether glyphosate could accumulate in the body over time and how glyphosate is monitored to ensure levels do not go above acceptable limits that could cause health effects.

PMRA Response

No indication of glyphosate accumulation was reported in any of the toxicity studies, as summarized in PRVD2015-01. When animals received single or repeat doses (14 days), in each case, the administered dose (AD) was excreted within 7 days post-dosing and negligible levels (under 1% of AD) remained in the examined tissues. Overall, the metabolic studies indicated poor absorption from the gut, almost complete excretion, and very minor metabolism in animals. Published regulatory reports by EFSA and the USEPA confirm these results. In summary, glyphosate is not expected to accumulate in the body over time. Refer also to response 2.2.8.

1.1.14 Use of Independent Scientific Studies

Comment

A number of comments stated that the PMRA, in its review of glyphosate, appeared to consider only "seller sponsored science". The comments referred the PMRA to a number of published studies that link glyphosate to health effects. Overall, these comments emphasized support for the use of "third party" data in assessing the health effects and making the final re-evaluation decision for glyphosate, in lieu of manufacturer-supplied data.

PMRA Response

Regulatory authorities world-wide regard studies that are performed under conditions of good laboratory practices (GLP) and according to internationally agreed upon study designs, such as the OECD test guidelines, as the most reliable, reproducible, and scientifically sound. Studies conducted according to these guidelines are of sufficient statistical power to detect effects of concern, they investigate many potential endpoints of toxicological concern, and have detailed individual animal results that enable regulatory authorities to thoroughly evaluate and interpret the data in an independent manner. Adherence to these guidelines produces studies in which regulators have a high degree of confidence.

Studies conducted by academic laboratories often have lower statistical power due to the use of fewer animals, investigate far fewer toxicological endpoints, and lack sufficient detail in their published form. These limitations prevent regulatory authorities from performing an in-depth analysis of study results.

As discussed in PRVD2015-01, the re-evaluation took into account all relevant sources of toxicity data in order to evaluate the potential health effects of glyphosate acid. This included an independent review of registrant-supplied data, which are required for the pesticide review and approval process in Canada, as well as consideration of scientific publications and information from other regulatory authorities.

For more information on the toxicology data requirements for registration of pest control products in Canada, please consult Guidance for Developing Datasets for Conventional Pest Control Product Applications: Data Codes for Parts 1 - 7 and 10[34] and/or 'OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring'.[35] Refer also to comment 2.2.9.

1.1.15 Health Effects of the Glyphosate Formulated Products

Comment

A number of comments questioned why glyphosate formulated products were not assessed for their health effects, stating that the health effects discussed in PRVD2015-01 were based on the active substance (glyphosate acid).

PMRA Response

Although the majority of mammalian toxicity studies for glyphosate were conducted using the active substance (glyphosate acid), toxicology studies that assess the acute hazard of formulated products are also examined. Individual formulated products are also used for other studies, such as in the generation of residue chemistry (field trial) data considered during the risk assessment phase. For more information on the data required for the active ingredient and formulated end use products for the registration of pest control products in Canada, please consult Guidance for Developing Datasets for Conventional Pest Control Product Applications: Data Codes for Parts 1-7 and 10.

In addition, as part of the glyphosate re-evaluation, an assessment was conducted on polyethoxylated tallow amines (POEA), which are a family of compounds often used as formulants in pest control products that function as surfactants. POEA substances (CAS no.

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34 Guidance for Developing Datasets for Conventional Pest Control Product Applications: Data Codes for Parts 1, 2, 3, 4, 5, 6, 7 and 10. Available online from http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/data-guide-donnees/index-eng.php [Last accessed Dec, 2016]

35 OECD (Organisation for Economic Co-operation and Development), 1997, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1. OECD Principles on Good Laboratory Practice (as revised in 1997). Available online from http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/mc/chem(98)17&doclanguage=en [Last accessed June, 2016]

61791-26-2) are included on List 4B of PMRA's list of Formulants (see REG2005-01[36] page 28). Currently, formulants are categorized into one of the five lists which rank them in descending order of concern. List 4B contains formulants are of minimal concern under specific conditions of use. For more details on the regulation of formulants in pest control products, refer to the PMRA Regulatory Directive DIR2006-02.[37]

As indicated in PRVD2015-01, the USEPA completed a human health risk assessment for phosphate ester, tallowamine, ethoxylated (ATAE), which is a subfamily of POEA. The PMRA considered the USEPA review, and reviewed the available toxicity studies that made up the USEPA assessment, including the pivotal study used in endpoint selection, which was a combined repeat-dose rat toxicity study with a reproduction/developmental toxicity screening component. As noted in the USEPA assessment, glyphosate products that contain no more that 20% POEA by weight are not of concern. Currently, all registered glyphosate products in Canada meet this limit.

1.2 Comments Related to Occupational / Residential Exposure

1.2.1 Bystanders

Comment
There were many general comments suggesting that the current level of non-dietary exposure to glyphosate is not safe for the general public (bystanders).

PMRA Response
Only those uses where human exposure to a pesticide is well below the level that cause effects in animal tests are considered acceptable for registration in Canada. This was confirmed with the re-evaluation of glyphosate

During the re-evaluation of glyphosate, it was recognized that there is potential for short-term exposure when entering treated non-cropland areas (in other words, hiking through forests or parks that have recently been treated with glyphosate). Calculated MOEs for all lifestages met the target MOE and are therefore not of concern to human health. In the interest of promoting best management practices and to minimize human exposure the following label statement is required:

"Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

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36 PMRA (Pest Management Regulatory Agency), 2005. Regulatory Note: *PMRA List of Formulants.* Available online from http://publications.gc.ca/collections/Collection/H113-7-2005-1E.pdf [Last accessed February 2016]

37 PMRA (Pest Management Regulatory Agency), 2006. Regulatory Directive: *Formulants Policy and Implementation Guidance Document.* Available online from http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2006-02-eng.pdf [Last accessed February, 2016]

1.2.2 Restricted-Entry Interval

Comment
Comments questioned the basis for changing the "Restricted-Entry Interval" to 12 hours for commercial class products, when PRVD2015-01 states that postapplication risks are not of concern for all uses. Comments indicated that, in general, glyphosate dries on the plant very quickly and there are no residues that can be readily passed on to workers. It was recommended that the label not specify a time limit but should instead indicate that field entry is allowed once the herbicide application has dried.

PMRA Response
A restricted-entry interval (REI) is the period of time that agricultural workers, or anyone else, must not do hand labor in treated areas after a pesticide has been applied. This is to allow residues and vapours to dissipate to safe levels for work to be performed. Hand labour tasks involve substantial worker contact with treated surfaces such as plants, plant parts, or soil.

All pest control products with agricultural uses require a minimum REI of 12 hours to protect workers, and others, from potential risks that may occur from both immediate and longer-term exposures to pesticide residues, vapors, and particulates. A minimum 12-hour REI allows residues to dry and vapors to dissipate, limiting potential effects such as irritation or allergic reactions.

1.2.3 Personal Protective Equipment

Comment
It was noted that in the proposed label amendments for products containing glyphosate, as presented in Appendix XII of PRVD2015-01, there is no mention of proposed changes for protective clothing at the time of mixing and loading, application, clean-up and repair. For commercial formulations of glyphosate, the current label wording makes no requirement for use of personal protective equipment during application. The lack of proposed label changes for protective clothing is an important oversight, especially the lack of requirement for protective clothing during spraying.

PMRA Response
The exposure estimates for mixers, loaders, and applicators of glyphosate used in the agricultural exposure assessment presented in PRVD2015-01 were based on a baseline level of PPE (long pants, long sleeved shirts and chemical-resistant gloves). The calculated dermal, inhalation, and combined MOEs are greater than the target MOE for all mixing, loading, and applying activities and therefore are not of concern. As such, no additional requirements for protective clothing beyond the baseline level of PPE are needed, as the existing labels already include the appropriate PPE.

1.2.4 Application Rates in Aggregate Exposure Assessment

Comment
In PRVD2015-01, all three aggregate exposure scenarios initially assumed 2 applications with a 7 day interval at the highest rate. At that application rate, the calculated MOEs for adult and youth/children (6 to <11 years old) scenarios reached the target MOE of 100, but the MOE for

children (1 to <2 years old) for the post-application + incidental oral exposure + chronic dietary scenario did not. It was interpreted that the PMRA changed the aggregate assessment to one application of glyphosate with a seven-day time-weighted turf transferable residue average for the entire aggregate assessment for all populations. It was suggested to use the highest application rate and frequency of glyphosate use to assess the aggregate exposures, and, if safety margins (MOE) were not met, to propose meaningful and wide-ranging use restrictions to increase human health protection.

PMRA Response

When conducting the aggregate exposure assessment, 2 applications (with a 7 day interval) at the highest rate were assumed. All calculated MOEs reached the target MOE except for children (1 to <2 years old) for the post-application + incidental oral exposure + chronic dietary scenario. Therefore, dietary and non-dietary exposure refinements were required.

The dietary exposure assessment used US Tolerances or Codex MRLs for situations where these values were greater than Canadian MRLs. However, domestic production and import statistics indicated that barley, oats, and wheat consumed in Canada are almost totally produced in Canada (>99%), with <1% imported. Thus, it was considered reasonable to use Canadian MRLs for these crops as a refinement in the calculation of the chronic dietary exposure estimates for the purpose of aggregation with residential exposure only, rather than the US and Codex group tolerance of 30 ppm. The current Canadian MRLs in these cereal crops are as follows: barley (and barley flour) - 10 ppm, barley milling fractions (except flour) -15 ppm, oat (and oat flour) - 15 ppm, oat milling fractions (except flour) - 35 ppm, wheat (and wheat flour) - 5 ppm, and wheat milling fraction (except flour) - 15 ppm.

In addition, assuming 2 applications (with a 7 day interval) at the maximum application rate is a highly conservative exposure assumption, as it is unlikely that children would be exposed to turf residues of the highest rate, at the lowest interval of application immediately after application. Therefore, a refinement using 1 application of glyphosate along with a 7 day time-weighted TTR average was used (the average resides of glyphosate were calculated over a 7 day span) for the entire aggregate assessment for all populations.

These refinements are health protective and all calculated MOEs met the target MOE and are not of concern to human health.

1.3 Comments Related to Dietary Exposure

1.3.1 Genetically Modified Crops

Comment

A number of comments expressed concern regarding the potential for higher residue levels of glyphosate in genetically modified (GM) crops, as reported in the article "*Compositional differences in soybeans on the market: glyphosate accumulates in Roundup Ready GM Soybeans. Bohn, T. et al., Food Chem. 2014, 153: 207-215.*"

PMRA Response

The residue chemistry of glyphosate, i.e. the nature and magnitude of residues of glyphosate in conventional (non-GM) crops, as well as in GM crops, is well understood and extensively documented. PMRA has received and reviewed all the metabolism studies required as per the PMRA Residue Chemistry Guidelines (Dir98-02[38]). The residue definition (RD) in plant commodities is based on scientifically sound metabolism studies conducted specifically in both types of crops. Whenever a new variant of GM crop is introduced on the market, the residue definition is reassessed based on mandatory supporting metabolism studies in that particular GM crop variant. The residue definition in animal commodities (resulting from feeding of the GM crop) is adjusted accordingly.

Currently there are three types of soybeans on the market: conventional (non-GM) soybean, EPSPS-GM soybean (containing the EPSPS gene) and GAT-GM soybean (containing the GAT gene). Based on metabolism studies in the respective crops, the RD in conventional and EPSPS soybeans are defined as the sum of glyphosate and its metabolite aminomethylphosphonic acid (AMPA). The RD in GAT soybean includes additional metabolites (acetylated glyphosate and acetylated AMPA) resulting from the specific biotransformation of glyphosate in GAT crops. As soybeans sold on the market cannot be distinguished with regards to whether they are conventional, EPSPS or GAT soybeans, the PMRA uses the most inclusive RD for soybeans, i.e., the RD in soybeans is the sum of glyphosate, AMPA and their acetylated counterparts.

All the metabolites included in the RD were deemed toxicologically equivalent to glyphosate. Consequently, in terms of residues, all the metabolites are expressed as the stoichiometric equivalent of glyphosate by using the appropriate molecular weight conversion factor (MWCF). The MWCFs are 1.5 for AMPA, 1.1 for N-acetyl AMPA and 0.8 for N-acetyl glyphosate. This means that the residue of glyphosate in soybeans (and in canola and corn comprising similar GM variants) is calculated as the sum: glyphosate + 1.5 AMPA + 1.1 N-acetyl AMPA + 0.8 N-acetyl glyphosate.

Residues of glyphosate (or any pesticide) in soybeans (or any crop) is a function of the agricultural practice by which they have been produced. GM soybeans are expected to have residue detects due to repeated spraying (in compliance with label directions) of plants throughout the production season. Conventional soybeans will contain lower residues levels because glyphosate is applied to weeds (before planting) and not on soybean plants. These facts are supported by field trial residue studies, which, as noted above, are required as per the PMRA Residue Chemistry Guidelines (Dir98-02). The field trial studies are conducted according to the petitioned-for use pattern and usage conditions (good agricultural practices) and constitute the basis for the registration and establishment of Maximum Residue Limits (MRLs). MRLs are established on the basis of worse case scenarios (maximum application rate, highest frequency of applications and shortest pre-harvest interval) within the agricultural practices. An MRL represents the maximum amount of residues that may remain on food when a pesticide is used according to label directions, and serves as a food safety standard. The results presented in the cited article did not exceed the established MRL of 20 mg/kg (20 ppm) for glyphosate in soybeans and confirm that current Canadian MRLs of glyphosate (including the metabolites) in

[38] PMRA (Pest Management Regulatory Agency), 1998. Regulatory Directive: *Residue Chemistry Guidelines*. Can be requested online from http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir98-02/index-eng.php [Last accessed August 2016]

soybeans are adequate. These MRLs were used in the estimation of short term (acute) as well as long term (chronic) dietary exposures. No dietary risk concerns were identified, as the levels of exposure estimates were well below the reference doses set for dietary risk assessment (the ARfD and ADI).

1.3.2 Mitigation Measures

Comment
A question was raised regarding a general (introductory) statement in Section 3.2 of PRVD2015-01 (Dietary Exposure and Risk Assessment) which reads: "*In situations where the need to mitigate dietary exposure has been identified, the following options are considered. Dietary exposure from Canadian agricultural uses can be mitigated through changes in the use pattern.*" The comment indicated that this statement implies that there are concerns with the glyphosate use pattern and, therefore, requested clarity on what mitigation measures were proposed.

PMRA Response
This is a general statement which would apply to any pesticide presenting dietary risk concerns. As no dietary risk concerns were identified for glyphosate, no mitigation measures were required.

1.3.3 Food Labelling

Comment
A comment requested that "glyphosate content" be added to all food labels (in grocery stores) so that consumers could decide whether they want to buy food containing glyphosate residues or not.

PMRA Response
Although Health Canada and the Canadian Food Inspection Agency (CFIA) share the responsibility for food labelling policies under the *Food and Drugs Act*, food labelling does not fall within the mandate of the PMRA or the *Pest Control Products Act* (PCPA). Other areas of Health Canada are responsible for developing policy and setting standards related to the health and safety aspects of labelling under the *Food and Drugs Act and Regulations*, whereas the CFIA applies these policies and enforces the regulations. The CFIA also has the mandate to develop general food labelling policies and regulations not related to health and safety. In particular, the CFIA is responsible for protecting consumers from misrepresentation and fraud with respect to food labelling, packaging and advertising, and for prescribing basic food labelling and advertising requirements.

With respect to glyphosate residues in foods, the CFIA is responsible for monitoring the Canadian food supply for pesticide residues and the determination of compliance with MRLs specified by Health Canada. In addition, both Canadian and international producers are aware of these MRLs and must comply with them in order to sell their produce in Canada or export to other countries that also have MRLs established. Therefore, it is expected that foods with residues higher than the MRL would not be present in the Canadian food supply.

For more details, please visit the CFIA Website at http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/genetically-engineered-foods/eng/1333373177199/1333373638071

1.3.4 Glyphosate Used as Desiccant and Residue

Comment
Comments expressed concern about the use of glyphosate for pre-harvest desiccation on conventional crops, the level of residues left on desiccated crops at harvest and the resulting long-term dietary exposure.

PMRA Response
Glyphosate is registered for pre-harvest use (desiccation) on a number of conventional crops including wheat, barley, oats, canola, flax, lentils, peas, dry beans, and soybeans. To support this use, field trial residue studies were required to determine the level of residues resulting from the pre-harvest desiccation conducted according to the requested use pattern. Maximum residue limits (MRLs) for these crops were established on the basis of the submitted studies. Those MRLs were included in the estimation of short term (acute) as well as long term (chronic) dietary exposures. During PMRA's assessment, no dietary risk concerns were identified, as the levels of exposure estimates were well below the reference doses set for dietary risk assessment (the ARfD and ADI).

1.3.5 Safety of GMO Crops

Comment
There were general questions as to whether GM crops are safe for human consumption.

PMRA Response
Health Canada conducts a rigorous and thorough science-based assessment of all GM food products before they are allowed to enter the Canadian marketplace. The assessments are conducted under the *Food and Drug Regulations*, which prohibit manufacturers of these products from selling them in Canada until Health Canada has completed a full safety assessment and has found them to be as safe and nutritious as conventional foods.

The approach taken by Health Canada in the safety assessment of GM foods is based upon scientific principles developed through expert international consultation over the last twenty years with agencies such as the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO) and the Organization for Economic Co-operation and Development (OECD). This same approach is currently applied by regulatory authorities around the world in countries such as the European Union, Australia/New Zealand, Japan and the United States. For more details, please visit the Health Canada Website at http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php.

1.3.6 Acceptable Level of Exposure

Comment
Comments included the question: "What is considered as acceptable level of exposure and how is that monitored to be sure that levels do not become unacceptable?"

PMRA Response

When assessing pesticide related health risks, two key factors are considered: the dose levels at which no health effects occur in animal testing (basis for the establishment of toxicological reference doses for humans) and the levels to which people may be exposed through diet, when handling and applying the pesticide, or by entering treated sites (in other words, level of exposure). The dose levels used to assess risks (in other words, toxicological reference doses) are established to protect the most sensitive human population (for example, children and nursing mothers). Only pesticide uses for which the level of exposure (through diet for example) is well below levels that cause no effects in animal testing are considered acceptable for registration.

Reference doses define levels to which an individual can be exposed to a pesticide residue over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (also known as acceptable daily intake).

The amount of pesticide to which an individual is exposed (in other words, exposure) is determined by determining the amount of pesticide that is in or on the food (in other words, residue levels) and combining that with the amount and type of foods that people eat (in other words, food consumption). Risk is then estimated by comparing the level of exposure to the reference doses described above. As previously noted, if the estimated intake is less than the reference dose, there are no dietary risks of concern.

In addition, inherent to pesticide registration is the establishment of maximum residue limits (MRLs) of the pesticide in/on foods on which the pesticide has been applied. An MRL represents the maximum amount of residues that may remain on food when a pesticide is used according to label directions, and serves as a food safety standard. The MRLs are calculated from residue data obtained from field trials that are conducted using the maximum application rate and the shortest pre-harvest interval. These MRLs, or field trial residue values, are used to estimate the level of dietary exposure at the time of pesticide registration. A pesticide is registered only if the calculated level of exposure is acceptable (in other words, exposure does not exceed the toxicological reference dose). The Canadian Food Inspection Agency (CFIA) is responsible for monitoring the Canadian food supply for pesticide residues and work very closely with Health Canada (PMRA) to ensure that the foods available on the Canadian market are compliant with the MRLs. In 2015, the Canadian Food Inspection Agency (CFIA) tested approximately 700 samples consisting of a variety of juice and juice blends, grains and grain products, beans, lentils, and a wide variety of fruit and vegetables. The CFIA also initiated a targeted survey of approximately 2,500 samples, looking at levels of glyphosate in bean, pea, lentil, chickpea and soy products, as well as less commonly consumed grains such as barley, buckwheat and quinoa. The results show a high degree of compliance with the MRLs established by the PMRA for glyphosate. The CFIA anticipates having their full analysis completed by Spring 2017.

1.3.7 Monitoring of Glyphosate Residue

Comment

Several comments noted: 1) the necessity to monitor amounts of glyphosate applied on fields, especially where resistant weeds have emerged; 2) the necessity to measure glyphosate residues resulting from ordinary field applications (field trial residue data); 3) the necessity to obtain glyphosate residue data that are reflective of foods as consumed through monitoring programs in

which food samples down the chain of commerce are sampled and analysed; 4) further information on maximum residue levels of glyphosate in food; and 5) the necessity to monitor glyphosate residues in body fluids and tissues (biomonitoring); as they are not included in the *Third Report on Biomonitoring of Environmental Chemicals in Canada.*

PMRA Response

As noted in response to comment 1.3.6, glyphosate residues on foods have been measured in field trial studies that are required to register a pesticide for specific uses, as per PMRA Residue Chemistry Guidelines (Dir98-02). These field trial data were used for the establishment of maximum residue limits (MRLs) for glyphosate, that is, the maximum legally allowed amount of glyphosate residue that may remain on foods when glyphosate is used according to label directions. The MRLs are enforced by law, and, the conditions of registration must be observed in all circumstances, regardless of whether resistant weeds have emerged or not. In cases of weed resistance, a higher rate than what is currently on the labels cannot be used, as this could lead to MRL exceedance and would be in violation of the *Food and Drugs Act*. The *Food and Drugs Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the specified MRL.

The Canadian Food Inspection Agency (CFIA) is responsible for monitoring the Canadian food supply for pesticide residues and the determination of compliance with MRLs specified by Health Canada. As noted in response to comment 1.3.6, in 2015, the Canadian Food Inspection Agency (CFIA) tested approximately 700 samples consisting of a variety of juice and juice blends, grains and grain products, beans, lentils, and a wide variety of fruit and vegetables. The CFIA also initiated a targeted survey of approximately 2,500 samples, looking at levels of glyphosate in bean, pea, lentil, chickpea and soy products, as well as less commonly consumed grains such as barley, buckwheat and quinoa. The results show a high degree of compliance with the MRLs established by the PMRA for glyphosate. The CFIA anticipates having the full analysis completed by spring 2017. A complete list of MRLs specified in Canada can be found on the PMRA's MRL Database, an online query application that allows users to search for specified MRLs, regulated under the *Pest Control Products Act*, for pesticides, including glyphosate, or food commodities (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php). For details on CFIA's monitoring program, please visit the CFIA website at http://www.inspection.gc.ca/food/fresh-fruits-and-vegetables/food-safety/chemical-residues/overview/eng/1374514433922/1374514696857.

Biomonitoring is a key tool used as an indicator and quantitative measure of exposure to chemicals in the environment. Human biomonitoring data contribute to our understanding of exposure and provide information to inform the management of the health risks posed by chemicals. The Canadian Health Measures Survey (CHMS) is an ongoing national biomonitoring survey led by Statistics Canada, in partnership with Health Canada and the Public Health Agency of Canada. Biomonitoring data have been reported for Cycle 1 (2007-2009), Cycle 2 (2009-2011) and Cycle 3 (2012-2013). Cycle 4 is currently underway, with data collection for this cycle having taken place from 2014 to 2015. These cycles are complementary, meaning that not all environmental chemicals (including pesticides) are included in a given cycle. For example, 55% of the chemicals measured in Cycle 2 were not included in Cycle 1 and about 31% of the chemicals measured in Cycle 3 were not included in previous cycles. Specific chemicals/pesticides are added to the list of measured chemicals in different cycles. Glyphosate, like many other pesticides, is being considered for inclusion in forthcoming cycles. For details on

the Canadian Health Measures Survey, please visit the Health Canada Website at http://www.hc-sc.gc.ca/ewh-semt/contaminants/human-humaine/chms-ecms-eng.php.

1.3.8 Glyphosate Use on Forest Vegetation and Effect on Health

Comment
One Aboriginal group provided the following comments:

I. Health Canada's glyphosate PRVD is based on dietary and occupational exposures that do not correspond with Anishinabek use of the territories for food, medicine and water;

II. Laboratory toxicological studies are based on reference values that do not conform to their own standards of risk, and do not take into account the cumulative effects of the environmental contaminants to which they are exposed;

III. They are concerned about the combined toxicity of glyphosate and the surfactants, solvents, and other additives.

PMRA Response
While the dietary risk assessment conducted by the PMRA does not directly assess the anticipated residues of glyphosate in edible forest vegetation, nor is the dietary burden to wild game specifically determined, based on assessments available, the PMRA does not expect that glyphosate residues from these foods would be of concern when ingested. This is because, in the dietary assessment that was conducted, residues in farm animal commodities were estimated and maximum residue limits (MRLs) were established by assuming the worst case scenario where the animal diet is considered to be comprised of 100% glyphosate-treated feedstuff, treated at the maximum application rate. This results in high-end residue estimates. For the same reason, residues in/on edible forest vegetation are expected to be low compared to MRLs established on conventional crops. These MRLs are established based on the worst case scenario, in other words, maximum application rate, shortest preharvest interval and maximum allowed number of applications per season. As noted in PRVD2015-01, using the above scenarios, there were no risk concerns from dietary exposure to glyphosate. The acute dietary exposure estimate (from food and drinking water) at the 95th percentile was 31% of the acute reference dose (ARfD) for females 13-49 years of age and ranged from 12% to 45% of the ARfD for all other population subgroups. The chronic dietary exposure estimate for the general population was 30% of the acceptable daily intake (ADI). Exposure estimates for population subgroups ranged from 20% of the ADI (for adults aged 50 years or older) to 70% of the ADI (for children 1-2 years old). Exposures less than 100% of the ARfD and ADI are not of concern. In the case of glyphosate, even when high-end (worst case) exposure estimates were used, no risk concerns to human health were identified.

The PMRA also conducted a health risk assessment for hikers walking through the forest immediately after application. The populations considered were adults, youths and children aged 6 to 10 years. From these estimates, no risk concerns were identified. As well, when exposures were aggregated (in other words, dietary exposure including from drinking water + non-dietary exposures as would occur from hiking in the forest), risks were also not of concern for the various population groups. Refer also to responses on environmental risk in Sections 2.2 and 2.4.

Regarding the cumulative effects of pesticides, please refer to the response to comments in Section comment 1.1.6 Cumulative Risk Assessment.

Regarding the combined toxicity of glyphosate and the surfactants, solvents and other additives, please refer to the response to comments in Section 1.1.15 Health Effects of the Glyphosate Formulated Products.

2.0 Comments Related to the Environmental Risk Assessments

2.1 Environmental Fate

2.1.1 Surficial and groundwater pollution and monitoring

Comment
Comments suggested or were concerned that glyphosate has the potential to leach to groundwater and natural areas, polluting water.

PMRA Response
In soil and water, glyphosate has been shown to break down quickly to aminomethylphosphonic acid (AMPA) through microbial processes and is considered to be non-persistent to moderately persistent. Glyphosate has low mobility in soil, giving it a low potential to contaminate groundwater systems, especially aquifers with low water hardness (Jayasumana et al. 2014). Glyphosate can enter surface waters when applied near water bodies or when carried in runoff, such as during a rain event on a steep slope. Glyphosate (without surfactant) and AMPA have comparable toxicological and ecotoxicological profiles, with both being considered to have low toxicity in general. According to the WHO (2004), the presence of glyphosate and AMPA at levels expected to be found in drinking water does not pose a risk to human health. Monitoring studies conducted throughout Canada indicate that glyphosate is rarely detected in groundwater. Although glyphosate is often detected in surface water, the concentrations detected are at relatively low levels that do not pose a risk of concern.

2.1.2 Glyphosate and AMPA persistence in soils and waters

Comment
Comments noted that glyphosate soil half-life values vary widely in terrestrial field dissipation studies in North America and that it may be more persistent than previously thought. Glyphosate may build up in soils and long-term negative effects are expected to occur. Glyphosate and AMPA are both frequently detected in soil and water in field dissipation studies from the United States (Battaglin et al. 2014).

PMRA Response
Glyphosate use per hectare in Canada is much lower compared to the US. Aquatic field studies conducted in Canada, including water monitoring studies, demonstrate glyphosate is detected less frequently and at lower concentrations than those reported in the US (Glozier et al. 2012, Hurley et al. 2012). The use of US field data for interpretation of the fate of glyphosate in Canada is challenging as the countries share only a few ecoregions, with climate and soil being different in much of the US where glyphosate is used as compared to Canada.

Terrestrial field dissipation studies
Laboratory studies conducted with glyphosate applied on different soils have DT_{50} (half-life) values ranging from 1 to 19.3 days, which classifies glyphosate as non-persistent to slightly persistent and indicates biotransformation by micro-organisms is effective.

Canadian terrestrial field dissipation studies show DT_{50} values ranging from 6 to 155 days for agricultural soils (average of less than 45 days) and from 24 to 82 days for forest soils (average of less than 55 days), similarly, in the US, DT_{50} values range from 1 to 174 days for agricultural soils (average of 41 days) and from <1 to 40.2 days for forest soils. The biotransformation of glyphosate is faster in forest ecosystems. In both environments, the compound is generally found in the upper soil horizons (0-15 cm depth) indicating overall that leaching to groundwater under field conditions is limited. The field data suggests glyphosate is non persistent to moderately persistent under field conditions and is not expected to carry over to the next year.

The wide range of dissipation rates, mainly in agricultural ecosystems, is likely a result of variation among soils, especially when considering foreign ecoregions (de Jonge et al. 2001; Vereecken, 2005, Borggaard and Gimsing, 2008, Farenhorst et al. 2009). Soil microbial activity may not always be efficient at transforming glyphosate or there may be other physical and chemical processes involved, reducing the rate of breakdown. Rapid adsorption to soil particles may play a role in preventing the transformation of glyphosate even in upper soil horizons where microbial activity is normally high and also when upper soil levels are not saturated with phosphate fertilizers (Helander et al. 2012). Preferential flow may play an important role, where root channels created by the death and decay of non-crop plants following glyphosate applications lead to the transport of glyphosate to lower soil horizons, however, leaching of glyphosate to deep soil horizons appears to be minimal.

Aquatic field dissipation studies
In general, aquatic field dissipation studies conducted in agricultural and forestry ecosystems in Canada and in the US indicate that glyphosate is non-persistent in natural waters (DT_{50} values ranging between ≤ 0.4 and 11.2 days).

Aquatic field dissipation studies conducted by Battaglin et al. (2014) and Battaglin and Koloc, (2014), show that glyphosate is readily transformed to AMPA by micro-organisms. Glyphosate was detected without AMPA in only 2.3% of samples, whereas AMPA was detected without glyphosate in 17.9% of samples. Both compounds were reported to be detected frequently in US soils and sediment, ditches and drains, precipitation, rivers, and streams, but less frequently in lakes, ponds, wetlands, soil water and groundwater. The study authors indicated that all concentrations of glyphosate measured were below the levels of concern for human and wildlife safety.

2.1.3 Runoff and aerial transport of glyphosate

Comment
Comments noted that the results of a runoff event studied in Argentina (Peruzzo et al. 2008) raise concerns about levels of glyphosate transported by runoff to aquatic environments. Glyphosate has been found in air and rain as demonstrated in a study conducted in Mississippi, USA (Chang et al. 2011, PMRA 2459642).

PMRA Response

The study of Peruzzo et al. 2008 suggests that rain events play an important role in transporting glyphosate present in the soil to stream water through runoff. In general, in the absence of mitigation measures to limit the run-off, especially when the ground is bare early in the season, this is not disputed. However, among all pesticides used in crop production in Argentina and elsewhere in the world, including Canada, glyphosate is among those that bind most strongly to soil. Despite glyphosate's high affinity for adsorption to soil particles, many studies have shown that the compound can find its way into water bodies, including studies from Italy (Screpanti et al., 2005; PMRA 2460734, Capri and Vicari, 2010; PMRA 2460735), the United States (Battaglin et al. 2005, PMRA 2423832, Scribner et al. 2007; PMRA 2460747, Newton et al. 1984; PMRA 1155371, Edwards et al. 1980; PMRA 2462226), Europe (Coupe et al. 2011; PMRA 2460748, Gregoire et al. 2010; PMRA 2462223, Siimes et al. 2006; PMRA 2462224), South America (Aparicio et al. 2013; PMRA 2462258) and Canada (Roy et al. 1989; PMRA 2460737, Struger et al. 2008; PMRA 1739313).

Many of the studies reported in the literature, including the one of Peruzzo et al. 2008, were conducted in ecoregions that are not equivalent to any Canadian ecoregions, meaning the soil and climatic conditions in study locations may not be relevant to conditions in Canada.

The amount of glyphosate applied in agricultural and forestry systems has increased since its first registration (about 40 years ago) and this is a factor in its frequent detection in surface waters and, more recently, in groundwaters of other countries outside North America (Sanchis et al. 2011, PMRA 2460750).

Examination of the factors controlling the transport of glyphosate to surface waters on a watershed scale is needed to determine which factors are important in this process and how these factors may change in importance, both spatially and temporally (Coupe et al. 2011, PMRA 2460748). The strong sorption of glyphosate to soil indicates that it expected to be poorly mobile. Recent studies on surface waters, both in Europe and in the Americas (North and South), suggest glyphosate could be transported to surface waters sorbed on soil particles. Detection in water may not only be a result of runoff, with drift, soil erosion, precipitation, and other processes having a role. In addition, the saturation of soils with phosphorus may play a role in reducing the sorption of glyphosate to soil particles, potentially increasing the amount carried in runoff.

Over the last two decades, Canadian growers have adopted best management practices on their farms (such as hedgerow, riparian strip, grass farm road, implementation of no till techniques leaving more plant biomass on the ground for runoff interception as well as the use of buffer zones) to avoid soil, fertilizer and pesticide losses from fields.

Runoff events can be difficult to predict and the presence of glyphosate in water as a result of runoff or spray drift is expected. Proper application timing and runoff/spray drift mitigation measures can reduce potential impacts.

Monitoring studies conducted throughout Canada indicate that glyphosate is rarely detected in groundwater. Although glyphosate is often detected in surface water, the concentrations detected are at relatively low levels that do not pose a risk of concern.

Glyphosate in the atmosphere

Available information indicates that limited amounts of glyphosate may enter the atmosphere at the time of spray application.

Glyphosate was not reported (among 49 compounds) in air or rain along the Mississippi river valley following an air survey campaign in 1995 (Foreman et al. 2000 and Majewski et al. 2000) but was recently reported to be frequently detected in air particles and rain from three agricultural areas of the Midwestern USA (Mississippi, Iowa and Indiana) with detection frequency ranging from 60 to 100% in air and rain in 2007 (Chang et al. 2011, PMRA 2459642 and Majewski et al. 2014). Glyphosate occurred at concentrations equal to or greater than the concentrations of other high-use herbicides previously studied in the Midwest (Waite et al. 2005). Unlike many other pesticides, the presence of glyphosate in air is reported to be due either to spray drift or wind erosion, because it is not volatile according to its low vapour pressure (1.3×10^{-7} Pa), Henry's law constant (2.1×10^{-9} Pa m^3/mole or 2.07 x 1014 atm. m^3/mole) and ionic character in moist soils (binding effect). Glyphosate was not measured or detected in the Canadian atmosphere during the Canadian Pesticide Air Sampling Campaign of 2003 (Yao et al. 2006).

In most studies, the maximum concentrations of glyphosate in air and rain correspond to the period of application and ranged from <0.01 to 9.1 ng/m^3 and from <0.1 to 2.5mg/L in air and rain samples, respectively. However, during a 2007 air survey by Majewski et al. (2000 and 2014) detectable concentrations of glyphosate were collected over the entire growing season, not just in spring as in previous years (before GMO's introduction around 1995), which is reported to be consistent with how glyphosate is now used on genetically modified crops for post-emergent weed control during the growing season. According to Chang et al. (2011), it is not known what percentage of the applied glyphosate was introduced into the air in 2007, but it is estimated that an average of 97% of the glyphosate in the air is removed by a weekly rainfall ≥30 mm. Based on the physical chemistry of glyphosate and the fact that the scale of use is lower in Canada as compared with the US, especially in the corn belt, the concentration of glyphosate in air is not expected to be of concern in Canada.

2.2 Ecotoxicological reviews

2.2.1 Beneficial insects impacted by the use of glyphosate

Comment

Comments noted that glyphosate negatively affects pollinator species (especially bees) and beneficial insect populations. GMO crops resistant to glyphosate, such as rapeseed crops or other GMO crops that include an insecticidal protein (for example, Bt) may have significant concentrations of these compounds in their flower pollen and nectar during the growing season following several applications of the herbicide. Bees foraging on these flowers may then transfer the glyphosate (with or without the insecticidal protein) through contaminated nectar and pollen when they feed young bees, which may have negative impact.

PMRA Response

The re-evaluation of glyphosate included a detailed analysis of studies to determine risks glyphosate may pose to pollinators and beneficial insects.

Acute oral and acute contact exposure of honey bees, and honey bee brood to technical glyphosate and glyphosate formulations obtained from the registrant did not result in mortality in laboratory studies. All acute oral and acute contact LD_{50} values were greater than the highest concentrations tested. The results of the studies indicate that glyphosate formulations and technical glyphosate are relatively non-toxic to bees. The use of glyphosate is expected to pose a negligible acute contact and oral risk to bees.

Direct exposure of bees to glyphosate through oral and contact tests represents a conservative exposure scenario as compared to the exposure bees receive from foraging on flowering rapeseed during a very specific time during the growing season.

A honey bee brood field study (Thompson, 2012) was reviewed by EFSA, 2015. Study results were also published in 2014 (Thompson et al. 2014), where the potential for glyphosate toxicity to developing honey bee larvae and pupae (tested with the Technical IPA salt and a glyphosate formulation (MON 52276)) when fed directly to honey bee colonies, showed a NOAEL (No Observed Adverse Effect Level) for brood development of honey bee colonies of 301 mg glyphosate a.e./L sucrose solution, the highest dose tested. EFSA concluded that glyphosate formulations (with POEA and without POEA) are relatively non-toxic to bees in terms of acute contact and acute oral routes to bees and honey bee brood.

Study results of Jadhav et al. 2008 showed no direct detrimental effects of glyphosate formulation with POEA on two water hyacinth biocontrol agents, *Neochetina eichhorniae* and *N. bruchi*. Jackson and Pitre (2004) demonstrated that the Roundup Ready soybean system, including applications of glyphosate, had no detrimental effects on pest and beneficial insects (*Cerotoma trifurcate* (Forster), *Spissistilus festinus* (Say), *Hypena scabra* (F.), and *Anticarsia gemmatalis* (Hübner) in wide-row soybean plantings. Study results of Hendrix and Parmelee (1985) showed that decomposition and microarthropod densities in glyphosate-treated grass litter (*Sorghum halepense*) were higher than untreated controls. Haughton et al. (2001a and 2001b) demonstrated that glyphosate spray applications were non-toxic to non-target spiders *Lepthyphantes tenuis* but that the loss of habitat was responsible for the reduction in abundance of the species. Similar observations and conclusions were found in tests carried out on the spider *Gonatium rubens* by Haughton et al. (1999).

Results of acute and chronic laboratory studies examining the toxicity of glyphosate formulations to the springtail *Folsomia candida* indicated that glyphosate formulations were not toxic to adult springtails up to the highest concentrations tested (Santos et al. 2012, PMRA 2469288). Results of acute and chronic laboratory studies examining the toxicity of glyphosate formulations to various other beneficial terrestrial arthropods on glass plates, leaf substrate and on artificial soil substrate generally indicate that glyphosate formulations were not toxic to the predatory mite (*Euseius victoriensis*) (Bernard et al. 2010; PMRA 2462245), the lacewing (*Chrysoperla carnea*) (SERA, 2010; PMRA 2469282), the hoverfly (*Episyrphus balteatus*) (Kedwards and Travis, 2001; PMRA 1213236), the carabid beetle (*Poecilus cupreus*) (Walker et al. 2000; PMRA 1213231) or the Staphylinid beetle (*Aleochara bilineata*) (Hermann, 2001; PMRA 1213232) up to the highest concentrations tested. Based on the weight of evidence, the risk to beneficial arthropods from the use of glyphosate is not expected to be of concern.

A study conducted by Murray et al. (2009) show that 50% of all wild bee species nest in a burrow in the ground. The intensification of agriculture may be contributing to the loss of foraging habitats and nesting sites for wild bees.

Studies by Duan et al. (2008) and Malone and Burgess (2009) show no adverse effects of glyphosate resistant Bt crops on exposed bees. These results are corroborated by Morandin and Winston (2003), Malone et al. (2007) and Babendreier et al. (2008), who looked at bumblebee colony exposure to Bt.

2.2.2 The Monarch Butterfly

Comment
Comments noted that the Monarch Butterfly is at risk due to the destruction of milkweed habitat resulting from the use of glyphosate.

PMRA Response
Monarch butterflies (*Danaus plexippus*) rely completely on plants in the milkweed family, especially the common milkweed (*Asclepias syriaca*) for both reproduction and larval food. Until recently, this plant was readily found in the Midwestern Corn Belt of the US and southern latitudes of Canada.

Monarch habitat has been documented to be in decline for the last 20 years in North America (Pleasants and Oberhauser, 2012, Brower et al. 2012, Bhowmik, 1994). Before the introduction of GMO crops, glyphosate was applied in spring at the pre-emergence stage of crops and had limited impact on the survival of the common milkweed (Waldecker and Wyse, 1985, Doll 1998). But recent introduction of GMO crops resistant to glyphosate enables herbicide treatments to be done very late in the growing season (Carpenter and Gianessi, 1999 and Duke and Powles, 2008), impacting the last emerged shoots of the common milkweed, and thus, compromising its survival.

For the monarch, the decline in milkweed represents a threat since the plant is now incapable of re-colonizing fields after GMO crop harvest, especially in the corn belt of the USA and now in the low latitude fields of Canada. The discussion is open as to what the grower should do regarding the competition of the milkweed and other weeds against his own crop within a specific field and/or the protection of the milkweed within the same field.

In fact, glyphosate is not meant to destroy monarch habitats outside of field limits. This is why buffer strips along agricultural fields close to hedgerows and other terrestrial and aquatic habitats exist, and why buffer zones are required to mitigate the impact of drift on non-target organisms located in aquatic and terrestrial habitats. In addition to agricultural pressures, Monarch habitat is also threatened by natural disasters (fire, drought, flood, etc.) and urbanization.

Canada is working with the US and Mexico to coordinate Monarch conservation efforts and is a member of the Trinational Monarch Science Partnership; the government of Canada's participation is led by Environment and Climate Change Canada. Domestically, the federal government has posted its proposed management plan for Monarch on the Species at Risk Public Registry, is funding research on Monarch habitat, and is using its Species at Risk funding programs to support Monarch and pollinator conservation.

2.2.3 Effect of glyphosate and its different formulations on soil microbes

Comment
Comments noted that PRVD 2015-01 did not address serious concerns related to glyphosate's chelation activity and antimicrobial (and antibiotic) properties. Recent published articles have reported that glyphosate and genetically modified (GM) crops can impact soil microbial populations (Fernandez et al. 2009). Glyphosate, like an antibiotic, may kill fungi in the soil, preventing soil microbes from delivering nutrients (minerals in particular) to plants and may increase plant diseases. Glyphosate may act on the shikimate pathway of gut bacteria. Research methods used in studies are not sensitive enough to properly determine the impact glyphosate has on soil microbial populations.

PMRA Response
Although the PMRA is aware that interactions between soil bacteria, fungi and plant root systems can improve plant health, the PMRA does not assess risks to soil microorganisms. Negative impacts have been observed on specific soil microbe strains, but overall, evidence suggests glyphosate end-use products have a low impact on deleterious and beneficial soil microbes following application. Glyphosate contributes to sustainable agricultural systems by reducing the need for cultivation (for example, no-till technique), increasing plant biomass on the ground, increasing the soil organic matter content, improving soil structure and reducing soil erosion and run-off. The fact that glyphosate use has been increasing since its first registration in Canada in 1976 demonstrates that growers have adopted the use of glyphosate and in turn the use of glyphosate-resistant crops very rapidly. If glyphosate had a meaningful negative impact on soil microbial activity over this 40 year use history, growers would not have been so quick to adopt and continue to use the product. The effects on soil microflora would have the strongest impact on crops grown on the fields. Areas away from the site of application are not likely to be negatively impacted.

2.2.4 Birds and mammals exposed to glyphosate and its formulations containing polyethoxylated tallow amine (POEA)

Comment
Comments noted that glyphosate has negative effects on non-target animals. Studies from the United Kingdom demonstrate that glyphosate contributes to a decline in bird species and is also believed to be responsible for increased livestock diseases, such as infertility, nutrient deficiencies (connected to Mn deficiencies), stillbirths, birth defects and abnormal bone formation. Glyphosate, in combination with surfactants used in glyphosate end use products (for example, POEA), is also more toxic to non-target organisms (animals and plants) than glyphosate alone.

PMRA Response
Birds
As presented in the PRVD2015-01, several oral, dietary and chronic toxicity studies were conducted with glyphosate technical and formulations on the bobwhite quail, *Colinus virginianus*, and the mallard duck, *Anas platyrhynchos*. Toxicity studies were also available for the canary, *Serinus canaria* (acute oral exposure with technical glyphosate) and the chicken (21-day dietary exposure with a glyphosate formulation). Glyphosate technical was not toxic to birds

on an acute oral, dietary or reproductive basis up to the highest concentrations or doses tested (PRVD2015-01). Similarly, glyphosate formulations are not particularly toxic to birds on an acute oral and dietary basis (reproduction tests were not available with glyphosate formulations). While acute oral exposure to glyphosate formulations resulted in bird mortality at high doses, glyphosate formulations were not toxic to birds up to the highest concentrations tested when exposure occurred through the diet. There is no indication that glyphosate formulations containing the surfactant POEA are more toxic to birds than formulations without it. Endpoints and risk quotients calculated using these studies are conservative as none of the toxicity studies conducted with technical glyphosate resulted in measured toxic effects in birds.

Although bird toxicity studies indicate that acute oral exposure to high doses of wet, unaltered, glyphosate formulations can result in effects, these effects are not observed when exposure occurs from dried residues of the formulation in the diet. Exposure to glyphosate formulations through the consumption of contaminated food items is a more relevant route of exposure for the environmental assessment than acute oral exposure to the wet formulation. The time period during which wet unaltered formulated product would be present on food items is very limited. Exposure is likely to be mostly from ingestion of dried residues on food items. It is noted that exposure via preening, which may be a relevant exposure route for wet formulation, is not considered in the current assessments. Thus, more weight is given to conclusions of the dietary assessment than to the acute oral assessment. The risk to birds from acute oral, dietary and reproduction exposure to glyphosate and its formulations is expected to be low.

One comment also reported the study of Newton (2004) as evidence of major farmland bird declines in the UK in connection with herbicide uses (not specifically glyphosate) and agricultural practices that would be responsible for the reduction of habitat and/or food available to many species.

Other studies indicate minimal impacts or even the absence of negative impacts on bird community structure and densities following glyphosate treatments in forests and vegetative changes after clearcuts (Morrison and Meslow, 1984; Mackinnon and Freedman, 1993). Other studies (Linz et al. 1992, Linz et al. 1994, Linz et al.1995, Linz et al. 1996a, Linz et al. 1996b, and Solberg and Higgins, 1993) show that glyphosate treatment in wetlands to control invasive species such as cattails (*Typha* spp.) was efficient and had positive impacts by restoring bird habitats (open water) and by increasing original population and diversity.

A review by Sullivan and Sullivan (2003; PMRA 2469318) reported that species richness and diversity of songbirds and small mammals were little affected by glyphosate-induced habitat alteration. Some species declined rapidly following treatment, whereas others increased in abundance. The effect of glyphosate on large mammalian herbivores was measured by the abundance of animals and food plants and by habitat use. Hares and deer were little affected, whereas reductions in plant biomass and related moose forage and habitat use generally occurred for the first few years after treatment, but not thereafter.

Studies in North America have identified habitat loss as the major cause of bird declines over the last 25 years (Santillo et al. 1989 and Hardy and Desgranges, 1990).

Mammals

Numerous acute oral toxicity studies on mammals were available for glyphosate technical and various glyphosate formulations. There is no indication that formulations containing the surfactant POEA are more toxic to mammals than formulations without POEA. Six multi-generation reproduction studies with exposure through the diet were available for technical glyphosate. No reproduction studies with glyphosate formulations were available.

Most mammalian toxicity studies show that exposure to high levels of glyphosate technical or its formulations does not result in toxic effects on mammals. Based on 60 acute oral studies, toxic effects were observed at high doses only in three studies conducted with glyphosate technical, and eight studies with glyphosate formulations. The majority of the available data indicate that risks to mammals following acute oral exposure to glyphosate and its formulations are low. Acute risks to mammals would be restricted to on-field exposure of only a few guilds (herbivores and insectivores). No reproductive risks to mammals are expected from the use of glyphosate. In addition, there are no incident reports for mammals related to the use of glyphosate.

2.2.5 Risk to Amphibians

Comment

Comments noted that glyphosate contributes to the decline of frog abundance. Glyphosate alone (Paganelli et al. 2010), and in combination with POEA, poses risks to amphibians according to studies of Relyea (2005a, 2005b and 2005c) and review of Annett et al. 2014.

PMRA Response

Toxicity data were available for 32 species of amphibians at various stages of development. As is shown with invertebrates and fish, the toxicity of technical glyphosate and its salts and glyphosate formulations containing non-POEA surfactants to amphibians is relatively low (acute LC_{50} = >17.9–7297 mg a.e./L) compared with glyphosate formulations containing POEA (acute LC_{50} = 0.8–51.8 mg a.e./L). Similarly, the results from subchronic and chronic laboratory studies and outdoor mesocosm studies with amphibians demonstrate that exposure to glyphosate formulations containing POEA elicit lethal and sublethal effects (for example, reduced body size, abnormal development, decreased time to metamorphosis) at relatively low concentrations (LC_{50} = 1.0–22.8 mg a.e./L, NOEC = 0.006 - >1.8 mg a.e./L).

Although acute studies showed no negative impacts on amphibians from glyphosate TGAI and formulations that do not contain POEA, a refined risk assessment conducted on amphibians (including frogs) exposed to glyphosate formulations containing POEA (lab tests) indicated that the level of concern was slightly exceeded (RQ = 1.1-1.2) for end-use products containing the surfactant POEA and tested in lab. Level of concern was not exceeded for refined mesocosm studies. Relyea (2005a and b) demonstrated a glyphosate formulation containing the surfactant POEA was responsible for the kill of 68-86% of juvenile amphibians exposed. This study, along with other amphibian studies, was considered in the re-evaluation of glyphosate and used to determine an HC_5 endpoint value from an SSD analysis. Results revealed an acute and chronic HC_5 of 0.93 and 0.86 mg a.e./L, respectively for glyphosate formulations containing the POEA surfactant that were used in the refined risk assessment. As a result, mitigation measures, in the form of no spray buffer zones, are identified on product labels and are required to protect amphibians. Risks to amphibians are not of concern if labelled spray buffer zone requirements are followed.

Annett et al. (2014), in their review, report the mode of action of different glyphosate formulations and their potential negative impact related to the inhibition of the enzyme acetylcholisesterase of some aquatic species as well as the oxidative stress due to Reactive Oxygen Species (ROS) causing damage to nucleic acid, lipids and proteins in aquatic species such as amphibian and fish that can lead to cell death. Studies reviewed, and reported by Annett et al. (2014) were also reviewed by the PMRA, with many of the reported endpoints being used by the PMRA in the risk assessment of glyphosate.

While there is evidence from laboratory studies suggesting that glyphosate products containing POEA are more toxic to amphibians than glyphosate alone, when considered in the context of all the studies available, particularly field studies conducted under actual use conditions, there is no compelling or credible evidence that gives rise to a serious possibility that glyphosate products containing POEA may cause an unacceptable environmental risk. In addition, while lower tier studies conducted in a laboratory showed potential for effects, a field study conducted under operational conditions (Thompson et al. 2004, PMRA 2032071) showed no significant adverse effects on amphibians. Moreover, glyphosate products containing POEA are used in forestry to prepare the site for reforestation which requires that the products be applied only once per silviculture cycle; typically equating to once every 50 to 80 years. As such, the potential for amphibian exposure to glyphosate products is limited in silviculture. Based on these findings, the PMRA concluded that there were no reasonable grounds to believe that the environmental risk to amphibians in small ephemeral forest wetlands from the spraying of glyphosate products was unacceptable.

2.2.6 Other Aquatic organisms

Comment

Comments noted that the following studies were not taken into account in the re-evaluation of glyphosate: Vera et al. 2010 (periphyton), Fairchild et al. 2002 (Atlantic salmon), and Sihtmae et al. 2013 (aquatic invertebrates).

PMRA Response

Periphyton

The study of Vera et al. 2010 entitled ''New evidence of Roundup impact on the aquatic periphyton community and the quality of freshwater ecosystems'' (Ecotoxicology 19:710-721) was in fact considered qualitatively in the re-evaluation, but no endpoints were available in the study to be used as part of the SSD analysis. The study of Bonnineau et al. 2012 (PMRA# 2462244) on periphyton was preferred and the freshwater algae acute 6hr-EC_{50} endpoint of 8.7 mg a.e./L was used in the re-evaluation of glyphosate and presented in PRVD2015-01.

Atlantic salmon

The study of Fairchild et al. 2002, entitled "Effects of freshwater contaminants on marine survival in Atlantic salmon" (NPAFC Tech Report No. 4) was examined and it was determined that the study is related to the active atrazine and does not report on glyphosate.

Aquatic invertebrates
The study of Sihtmae et al. 2013 entitled "Ecotoxicological effects of different glyphosate formulations'' (Applied Soil Ecology 72:215-224) was indeed used in the re-evaluation of glyphopsate. The freshwater invertebrate endpoint values reported by Sihtmae et al. 2013 (PMRA 2574468) were used in the determination of HC_5 values from a SSD analysis. Refer to response 2.3.2 below.

2.2.7 Endocrine disruption

Comment
Comments noted that the PMRA should phase out the use of products containing glyphosate based on articles that have identified glyphosate as an endocrine disruptor.

PMRA Response
The USEPA's Endocrine Disruptor Screening Program (EDSP) is currently working to validate the assays proposed by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), many of which are being validated in coordination with the OECD through the Endocrine Disrupters Testing and Assessment (EDTA) and the Validation Management Groups (VMGs). The results of screening tests for glyphosate are available on the following website: (http://www2.epa.gov/sites/production/files/2015-06/documents/glyphosate-417300_2015-06-29_txr0057175.pdf).

Although the study by Antoniou et al. 2012 raised concerns regarding the potential impact of glyphosate as an endocrine disruptor, the conclusion is that glyphosate demonstrates no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways in mammals or wildlife. Based on weight of evidence considerations, mammalian or wildlife EDSP Tier 2 testing is not recommended for glyphosate. Also refer to response to comment 1.1.12.

2.2.8 Bioaccumulation

Comment
Comments questioned if glyphosate can accumulate in the body over time and how levels of glyphosate are monitored to ensure that it does not go above acceptable limits that could cause detrimental health effects to animals?

PMRA Response
Information available on the bioaccumulation potential of glyphosate is presented in the PRVD 2015-01. Glyphosate is not expected to bioaccumulate due to its high polarity (log K_{ow} = -2.8 to -0.67) and anionic character (Mensink and Janseen, 1994, PMRA 2462253 and Villeneuve, J., 2012 (PMRA 2203372)). A maximum bioconcentration factor (BCF) of 1.6 was reported for bluegill sunfish exposed to 0.6 mg/L for 28 days (Wang et al. 1994b; PMRA 2460743 and Takacs et al. 2002; PMRA 2462252). BCF values of 12 to 35.4 and 10 to 42.3 for tilapia and carp, respectively were also reported by Wang et al. 1994b (PMRA 2460743). Channel catfish, largemouth bass and rainbow trout exposed to 10 mg/L glyphosate for 14 d had BAFs of 0.18, 0.04, and 0.03, respectively (Kramer and Beasley, 1975, PMRA 1182548).

2.2.9 Science based approach and the use of independent scientific studies in the environmental risk assessment.

Comment

Various stakeholder organizations emphasized the importance of a science-based approach and agreed with the proposed regulatory label changes. Other commenters encouraged to use a number of different sources of information that claim glyphosate poses an environmental risk. Sources of information from various non-governmental organizations or independent researchers were provided. In addition to registrant submitted studies, work done by third parties (independent research) should be used in assessing the environmental effects of glyphosate and in making the final re-evaluation decision.

Some commenters believe that the environmental risk assessment for glyphosate was conducted using only studies provided by the registrants and that there has not been enough long-term testing of glyphosate done by independent scientists. Reviewing studies conducted and provided by the company that is seeking registration of the product is perceived as a conflict of interest and highly biased as these studies are not peer reviewed by the scientific community. Reference was provided to a number of published scientific studies that link glyphosate to environmental and agronomic effects.

PMRA Response

The environmental risk assessment of glyphosate was conducted using a science-based approach and included consideration of a large volume of literature. In addition to registrant supplied data, more than 1500 scientific articles related to glyphosate were examined, with approximately 250 of these studies being deemed relevant and useful for consideration in the environmental risk assessment. Values obtained from the public literature were used in combination with the registrant data set in order to strengthen the environmental risk assessment. Due to the tremendous amount of endpoint data available for different aquatic and terrestrial organisms, SSD analysis was employed to determine HC_5 and HD_5 values that were used in the risk assessment. Also refer to response to comment 1.1.14.

2.2.10 Assessment of formulations

Comment

Commenters questioned why the formulations of glyphosate products are not assessed for their environmental effects. Environmental effects discussed in the PRVD2015-01 were based primarily on the active substance (in other words, glyphosate).

PMRA Response

PRVD2015-01 includes risk assessments for not only the technical active ingredient, but also the various formulations, including those that contain POEA. Endpoints using values from EUPs were used to derive HD_5/HC_5 values from SSD calculations when possible. The risk assessment includes a comparison of the exposure of terrestrial and aquatic organisms to technical glyphosate and the formulations.

2.3 Risk assessment and methodology

2.3.1 Endpoint selection

Comment
Some endpoints used in the terrestrial and aquatic plant risk assessment as well as the risk assessment for aquatic organisms were inappropriate. The quality of some of the data used in the risk assessment was not clear and was questionable. Specific studies that were at issue were identified for the PMRA to reconsider. The process used to review and ensure the quality of open literature studies used in the risk assessment needs to be more transparent.

PMRA Response
Endpoints derived from unpublished registrant/applicant submitted data follow guidelines set by regulatory bodies and are subject to good laboratory practice standards. These studies have clear objectives, scientific and analytical protocols, and the data has been subject to appropriate statistical analysis. On the other hand, published scientific papers are written in a concise way in order to bring enough information and details for the reader to accept or reject the conclusion of the author(s). Although published scientific articles are subject to a scientific peer review that strengthens their validity, information in published studies must have sufficient detail so that the scientific methods (protocol) and the results obtained are reproducable. Unfortunately, many published scientific studies lack sufficient detail, reducing confidence in the conclusion reached by the author(s). As a result, some published scientific papers are rejected when reviewed by the PMRA during the re-evaluation process. (Refer also to response to comment 1.1.14).

That said, as a result of comments received during the comment period for the PRVD2015-01, endpoints questioned in the comments have been re-examined and changes to the risk assessment have been made based on a revised assessment of their validity. References associated with endpoint values are presented in the tables found in (Appendix III).

2.3.2 SSD model

Comment
The methodology for deriving Species Sensitivity Distributions (SSDs) is not fully described in the PRVD and the requirements for inclusion of endpoints is not discussed. The use of a combination of terrestrial plant EC_{25} and EC_{50} endpoints for vegetative vigour in SSD calculations should be reconsidered.

PMRA Response
The toxicity data analysis includes the determination of HC_5 or HD_5 values using an SSD or species sensitivity distribution. An SSD is a plot of all species' toxicity endpoints within a taxonomic group against a cumulative density function. An SSD is determined by fitting a theoretical distribution to the data set, such as a log-normal distribution, and allows the derivation of community level threshold concentrations such as the HC_5. The hazardous concentration (HC_5) or dose (HD_5) to five percent of species is calculated for acute and chronic data sets separately, using the acute LC_{50}/EC_{50} values and chronic NOEC/NOEL values, respectively. An SSD is constructed for acute and chronic effects for every taxonomic group where sufficient toxicity data are available. Acute toxicity data generally refers to short term studies, with the endpoints (LC_X or EC_x) being derived from effects on survival or other

endpoints considered to affect survival. Chronic and sub-chronic studies generally aim to determine sublethal effects and the associated NOEC or NOEL concentration. Different endpoints can also be used in SSDs such as the EC_{25} for terrestrial plants or other EC_X value such as an $EC_5/_{10}$ may be considered relevant and appropriate to the assessment. If SSDs cannot be calculated, the most sensitive endpoints with an appropriate uncertainty factor are used in risk assessment.

The software program ETX 2.1 is used with the log-normal model to generate SSDs where sufficient toxicity endpoints are available for different taxonomic groups. The median HC_5 values are reported for SSDs. The variability in the data sets is indicated not only by the upper and lower bound HC_5 estimates but also the confidence limit of the fraction of species affected (FA), which indicates the theoretical minimum and maximum percent of species that could be affected based on the available data when the population is exposed to the HC_5 concentration.

SSDs were determined for glyphosate herbicide for the following taxonomic groups (results are reported in Appendix III Tables 1 to 3):

- Freshwater organisms: invertebrates, fish, algae, amphibians, aquatic plants
- Marine organisms: fish, invertebrates and algae
- Terrestrial organisms: plants (crop and non-crop)

Where an HC_5 value cannot be determined due to insufficient species data or lack of model fit, etc., the most sensitive species endpoint is reported in summary tables without the use of uncertainty factors. Where multiple data points are available for one species, a geometric mean value is used to represent the species' sensitivity. The treatment of toxicity data is such that it allows quantitative comparisons and predictions including consistency of exposure concentration units, ecological relevance and comparability of measurement endpoints, and types of test chemicals, or duration of exposure.

All data sets were grouped by test material type including technical grade active ingredient (TGAI, includes all forms of glyphosate actives), end-use products containing the surfactant POEA (EUP + POEA), end-use products which do not contain POEA (EUP NO POEA), POEA alone and the glyphosate transformation product AMPA. All toxicity values were normalised to acid equivalent (a.e.).

Results of SSD analysis:

Glyphosate shows equal toxicity to many aquatic taxonomic groups, both acutely and chronically. The most acutely sensitive aquatic taxonomic groups are freshwater plant (overspray on aquatic macrophyte; Er_{50} of 38 g a.e/ha), freshwater and marine invertebrates, and freshwater algae (HC_5 = 0.1mg a.e./L). The lowest chronic toxicity threshold values were determined for freshwater and marine fish (NOEC = 0.28 and 0.1 mg a.e./L, respectively) and freshwater plants (chronic EC_{50} = 0.11 mg a.e./L). The most sensitive terrestrial plant endpoint for crops and non-crops is the HD_5 of EC_{50} value of 0.0658 kg a.e./ha for EUPs that contain, or do not contain POEA, based on plant vegetative vigor endpoints.

As observed for amphibian in previous section 2.2.5, it is noted that the formulated products of glyphosate are generally more toxic to some organisms than the active ingredient, as in the case of freshwater invertebrates which are two orders of magnitude (100x) more sensitive to formulations containing POEA vs. the active ingredient. Freshwater fish and plants are also more sensitive to EUPs. Marine fish on the other hand are most sensitive, on an acute basis, to the parent chemical.

Therefore the SSD analysis results indicate that the most sensitive population level aquatic toxicity threshold value (HC_5) is 0.1 mg a.e./L, based on acute and chronic endpoints for several taxanomic groups including freshwater and marine invertebrates, aquatic plants (except overspray), algae and fish. While the most sensitive population level terrestrial toxicity threshold value (HD_5 of EC_{50}) is 0.0658 mg Kg a.e./ha, based on acute toxicity to plants (crops + non-crops exposed to glyphosate formulations containing POEA + glyphosate formulations without POEA).

2.3.3 Buffer zone calculations

Comment
Comments noted that the buffer zone sizes should be recalculated based on reconsideration of acceptability of endpoints. Buffer zone sizes should be set based on scientific evidence and valid endpoints and no increase should be implemented if no such evidence exists. Please explain why buffer zones are different for treated areas of more than 500 ha and those that are less than 500 ha.

PMRA Response
The PMRA agrees with the fact that buffer zone sizes should be set based on scientific evidence and valid endpoints and no increase or decrease should be implemented if no such evidence exists. The methodology used by the PMRA to calculated buffer zones is based on scientific evidence and valid endpoints.

Endpoints were reconsidered following identification of questionable studies, which lead to changes in the endpoints included in the SSDs and the determination of HC_5 values, especially for aquatic organisms. Buffer zones have been recalculated as a result of the changes in the SSD calculations.

The reason why buffer zones are different for treated areas of more than 500 ha and those that are less than 500 ha. is the following:

The AGDISP software model (version 8.21) used by the PMRA to calculate aerial buffer zones takes into account the cumulative downwind drift associated with the number of flightlines made over a treated surface area with an aircraft. A forest surface area of more than 500 ha is considered as 'woodland' and is modelled using 50 flightlines as a realistic scenario. A forest surface area of less than 500 ha is considered as 'woodlot' and requires only 10 flightlines. As such, cumulative drift may be more significant in woodlands than in woodlots and consequently buffer zones may be larger in woodlands than in woodlots. Updated buffer zone tables are reported in Appendix IV, Tables 1 and 2.

2.4 Aerial spraying of forests

Comment
One Aboriginal group commented that aerial spraying of forests with glyphosate impacts the environment.

PMRA Response
As noted in response to comment 2.2.5, glyphosate is used for forest site preparation and plant release (conifers and deciduous trees) after trees are harvest. This use is expected to occur once every 50-80 years. As such, glyphosate exposure to forest is extremely low. In addition, glyphosate does not persist in the terrestrial environment, with DT50s ranging from 24 to 82 days in forest soils (average of less than 55 days).

For the protection of aquatic habitats, no spray buffer zones of 1 to 10 meters are required when glyphosate formulations that contain POEA are applied for forest site preparation and plant release by air. A buffer zone is defined as the distance between the point of direct pesticide application and the nearest downwind boundary of a sensitive habitat. Glyphosate does not persist in water (DT50s range from 0.4–11.2 days).

3.0 Comments Related to the Value Considerations

3.1 Glyphosate has value in contributing to Canadian agriculture and non-agricultural land management

Summary of Comments

- glyphosate is an important and cost effective weed management tool in crop production in that it can be applied at varying points of the cropping cycle from preplant to post-harvest.
- the application of glyphosate prior to harvest is important in terms of advancing the maturity and/or uniformly desiccating the crop and to control late season weeds that can interfere with harvesting operations and reduce crop quality.
- glyphosate with its unique mode of action remains an important tool for broad spectrum weed control, including of perennial, invasive and noxious weeds
- it allows the Canadian agricultural sector to remain competitive with those of its trading partners
- it remains an important tool for advancing conservation tillage, such as no-tillage and reduced tillage systems, that reduce soil erosion and increase soil organic matter
- it is used to control invasive plants to foster biodiversity by allowing native plant communities including those containing endangered or rare species, to be preserved or re-established.

PMRA Response
As stated in the PRVD2015-01, the PMRA acknowledges that glyphosate plays an important role in weed management in both Canadian agriculture and non-agricultural land management

3.2 Glyphosate has no value considering the risks to the environment and human health.

PMRA Response
The value of glyphosate to Canadian agriculture and non-agricultural land management is a result of this product's unique mode of action, diverse use pattern, and broad spectrum of weed control. As indicated in PRVD2015-01, based on a review of the science, the PMRA has concluded that this product is unlikely to affect human health or pose an unacceptable risk to the environment when used in accordance with label directions.

4.0 Other Comments Related to the Use of Glyphosate

4.1 Weed resistance

Comment
Comments noted that repeated use of glyphosate and heavy reliance on glyphosate to control weeds in today's agriculture practices increase weed resistance. PMRA has not addressed the issue of weed resistance in its re-evaluation of glyphosate. There is no mention of glyphosate-resistant weeds anywhere in the Environmental Considerations of the PMRA's Proposed Re-evaluation decision for glyphosate. A report recently published by the Canadian Biotechnology Action Network (CBAN) reveals that "there are five species of glyphosate-resistant weeds now found in Canada". An online survey of farmers from 2013 estimated that more than one million acres of Canadian farmland had glyphosate resistant weeds.

PMRA Response
The PMRA is aware of the fact that the current agricultural production system relies heavily on glyphosate, resulting in more and more occurrences of glyphosate-resistant weeds. Kochia, Canada fleabane, giant ragweed and common ragweed are examples of such resistant weeds reported in Canada. These glyphosate-resistant weeds are increasingly becoming challenge to the agricultural production system. In order to prevent or delay the development of glyphosate-resistant weeds, it is crucial to maintain diversity in weed management practices. From the regulatory perspective, the PMRA developed the resistance-management labelling program in 1999 with an aim to mitigate the risks for resistance development. Participation in this program is on a voluntary basis, but registrants are encouraged to add the resistance-management grouping symbols and resistance management statements to both new and existing product labels (Regulatory Directive DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site/Mode of Action)*. To date, the majority (about 95%) of labels for products containing glyphosate comply with the resistance-management labelling. Other organizations are more closely involved with improvements to agricultural practices.

4.2 Invasive species

Comment
Comments noted that herbicide treatments such as glyphosate are needed to control invasive species in standing water, such as *Phragmites australis* (2015 Resolution of the Canadian Federation of Agriculture Annual General Meeting).

PMRA Response

Before a pesticide is approved for use in Canada, it must undergo a thorough pre-market science-based risk assessment and meet strict health and environmental standards, and the product must have value. The use of glyphosate to control invasive species in standing water was not registered in Canada, and therefore was not considered during the re-evaluation.

The PMRA is aware of the rise of *Phragmites* in Canadian wetlands, and has been working with provincial partners to find solutions such as emergency registration where needed. An emergency use will be considered only if the product is efficacious and risks deemed acceptable.

4.3 Treaty rights and the duty to consult First Nations

Comment

One Aboriginal group commented that aerial spraying on traditional lands is a violation of treaty rights and it is a constitutional obligation for Health Canada to consult. The PMRA is obligated to hear oral testimony in their territory as a form of evidence.

PMRA Response

Concerns expressed by the aboriginal group in their written submission and in subsequent conversations, were identified as being related more to forest management practices and not specific to the use of this particular herbicide.

Following harvest, Canadian forests are either allowed to regenerate naturally or are re-planted with a crop tree species as part of a forest management plan. Glyphosate, or other herbicides, can be applied in a managed forest to control naturally occurring vegetation that could out compete newly planted crop tree seedling (for example, pine or spruce trees) for nutrients, light and space. Herbicides are also used in clearing logging roads and rights of way. As with other land management uses of pesticides such as agriculture, the use of herbicides in forestry operations can reduce biodiversity (for example, loss of grasses, raspberry and non-crop tree species, such as birch or aspen) in the application areas for a period of time.

Except on federal lands, the management of natural resources, such as forests, is the responsibility of provincial governments. Provincial ministries of natural resources are better informed about the local conditions and are generally responsible for approving sustainable forest-management plans. These plans indicate which land will be allowed to regenerate naturally and which will be re-planted and managed (with or without herbicides). If a herbicide is to be used, it must a product that is authorized by Health Canada's Pest management Regulatory Agency for forestry application. It the product is to be applied by air, permits are required, generally from provincial ministries of the environment, prior to application. Consultations with the aboriginal community on herbicide use in forestry can be most effectively done by considering forest management plans and the local land use requirements. It is recommended that the group continue to raise their concerns with the appropriate provincial authorities

Other concerns that were raised by this group regarding the impact of glyphosate use on human health and the environment were addressed under responses 1.3.8 and 2.4.

Appendix II Registered Products Containing Glyphosate in Canada as of 16 September 2016

Registrant Name	Registration Number	Product Name	Guarantee (g a.e./L)	Formulation	Marketing Class
ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	29219	GLYPHOGAN PLUS LIQUID HERBICIDE	GPI-356;	SN-SOLUTION	C+R
ALBAUGH LLC	28322	CLEAROUT 41 PLUS HERBICIDE SOLUTION	GPI-360;	SN-SOLUTION	C
	31913	GLYPHOSATE 480	GPI-480;	SN-SOLUTION	C
ALLIGARE, LLC	30093	ALLIGARE GLYPHOSATE 4+	GPI-360;	SN-SOLUTION	C
AGROMARKETING CO. INC.	30721	NASA 36	GPI-360;	SN-SOLUTION	C+R
AGRI STAR CANADA ULC.*	29995	CRUSH'R PLUS	GPI-360;	SN-SOLUTION	C
	32181	CRUSH'R 480	GPI-480;	SN-SOLUTION	C
	31655	AGRI STAR CRUSHR 540	GPP-540;	SN-SOLUTION	C
DOW AGROSCIENCES CANADA INC.	30958	ENLIST DUO HERBICIDE	GPX-204; DXJ-194;	SN-SOLUTION	C
	30960	GF-2726 TSOY HERBICIDE	GPX-204; DXJ-194;	SN-SOLUTION	C
	27394	PREPASS B HERBICIDE (A COMPONENT OF PREPASS HERBICIDE)	GPI-360;	SN-SOLUTION	C
	27615	VANTAGE PLUS MAX HERBICIDE SOLUTION	GPI-480;	SN-SOLUTION	C
	28245	MAVERICK II HERBICIDE SOLUTION	GPI-480;	SN-SOLUTION	C
	28540	ECLIPSE II B HERBICIDE	GPI-480;	SN-SOLUTION	C
	28977	MAVERICK III HERBICIDE	GPX-480;	SN-SOLUTION	C
	29033	ECLIPSE III B HERBICIDE	GPX-480;	SN-SOLUTION	C
	29652	PREPASS XC B HERBICIDE (A COMPONENT OF PREPASS XC HERBICIDE)	GPX-480;	SN-SOLUTION	C
	29994	VANTAGE XRT HERBICIDE	GPX-480;	SN-SOLUTION	C
	26171	VANTAGE PLUS HERBICIDE SOLUTION	GPI-360;	SN-SOLUTION	C+R
	26172	VANTAGE HERBICIDE SOLUTION	GPI-356;	SN-SOLUTION	C+R
	26884	VANTAGE FORESTRY HERBICIDE	GPI-356;	SN-SOLUTION	C+R
	29588	GF-772 HERBICIDE	GPI-360;	SN-SOLUTION	C+R
	29773	DEPOSE HERBICIDE SOLUTION	GPI-356;	SN-SOLUTION	C+R
	30516	VANTAGE MAX HERBICIDE	GPS-480;	SN-SOLUTION	C+R
	28840	VP480 HERBICIDE	GPX-480;	SN-SOLUTION	C+R
	29774	DURANGO HERBICIDE	GPX-480;	SN-SOLUTION	C+R
	30423	PREPASS 480	GPX-480;	SN-SOLUTION	C+R

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
		HERBICIDE			
	32314	GF-2018 HERBICIDE	GPX-480;	SN-SOLUTION	C+R
EZJECT, INC.	21262	DIAMONDBACK HERBICIDE SHELLS	GPI-0.15;	PA-PASTE	C
FMC CORPORATION	27287	GLYFOS AU SOLUBLE CONCENTRATE HERBICIDE	GPI-360;	SN-SOLUTION	C
	28925	CHEMINOVA GLYPHOSATE (TM) II	GPI-356;	SN-SOLUTION	C
	29363	GLYFOS BIO HERBICIDE	GPI-360;	SN-SOLUTION	C
	29364	GLYFOS BIO 450 HERBICIDE	GPI-450;	SN-SOLUTION	C
	30234	FORZA BIO SILVICULTURAL HERBICIDE	GPI-360;	SN-SOLUTION	C
	30235	FORZA BIO 450 SILVICULTURAL HERBICIDE	GPI-450;	SN-SOLUTION	C
	24359	GLYFOS SOLUBLE CONCENTRATE HERBICIDE	GPI-360;	SN-SOLUTION	C+R
	26401	FORZA SILVICULTURAL HERBICIDE	GPI-360;	SN-SOLUTION	C+R
	28924	GLYFOS SOLUBLE CONCENTRATE HERBICIDE II	GPI-360;	SN-SOLUTION	C+R
INTERPROVINCIAL COOPERATIVE LIMITED	26846	GLYPHOSATE HERBICIDE - AGRICULTURAL & INDUSTRIAL	GPI-360;	SN-SOLUTION	C
	29216	GLYPHOSATE WATER SOLUBLE HERBICIDE	GPI-309(+51);	SN-SOLUTION	C
	27988	IPCO FACTOR 540 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	31199	FORTRAN 540 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	31598	CO-OP VECTOR 540 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	29775	MATRIX HERBICIDE SOLUTION	GPX-480;	SN-SOLUTION	C+R
	30319	VECTOR HERBICIDE SOLUTION	GPX-480;	SN-SOLUTION	C+R
	31090	RIVET HERBICIDE	GPX-480;	SN-SOLUTION	C+R
JOINT GLYPHOSATE TASK FORCE, LLC	30678	JGTF GLYPHOSATE HERBICIDE	GPI-360;	SN-SOLUTION	C+R
LOVELAND PRODUCTS CANADA INC.	30076	MAD DOG PLUS	GPI-360;	SN-SOLUTION	C+R
MEY CANADA CORPORATION	29126	WISE UP HERBICIDE SOLUTION	GPI-360;	SN-SOLUTION	C
MONSANTO CANADA INC.	20423	MOCAN 943 WATER SOLUBLE HERBICIDE	GPI-120; DIC-86;	SN-SOLUTION	C
	21572	RUSTLER FALLOW LIQUID HERBICIDE	GPI-132; DIC-60;	SN-SOLUTION	C
	27200	RUSTLER LIQUID HERBICIDE	GPI-194; DIC-46;	SN-SOLUTION	C

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
	32274	ROUNDUP XTEND WITH VAPORGRIP TECHNOLOGY HERBICIDE	GPI-240; DIC-120;	SN-SOLUTION	C
	19536	RUSTLER SUMMERFALLOW HERBICIDE	GPI-108; DXB-182;	SN-SOLUTION	C
	25898	MON 77790 HERBICIDE	GPI-132; DXB-82;	SN-SOLUTION	C
	25604	ROUNDUP FAST FORWARD PREHARVEST HERBICIDE	GPI-300; GLG-16;	SN-SOLUTION	C
	25795	ROUNDUP FASTFORWARD PRESEED	GPI-300; GLG-10;	SN-SOLUTION	C
	25918	MON 77759 WATER SOLUBLE HERBICIDE	GPI-300; GLG-36;	SN-SOLUTION	C
	26625	MON 78027 WATER SOLUBLE HERBICIDE	GPI-180; GLG-131;	SN-SOLUTION	C
	26920	ROUNDUP TRANSORB MAX LIQUID HERBICIDE	GPI-480;	SN-SOLUTION	C
	29841	MON 76431 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C
	29868	MON 76429 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C
	19899	VISION SILVICULTURE HERBICIDE	GPI-356;	SN-SOLUTION	C+R
	25344	ROUNDUP TRANSORB LIQUID HERBICIDE	GPI-360;	SN-SOLUTION	C+R
	27487	ROUNDUP WEATHERMAX WITH TRANSORB 2 TECHNOLOGY LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	27736	VISIONMAX SILVICULTURE HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	27764	ROUNDUP ULTRA LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	27946	RENEGADE HC LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	28198	ROUNDUP TRANSORB HC LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	28486	ROUNDUP ULTRA 2 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	28487	RT/540 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	28608	MON 79828 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	28609	MON 79791 LIQUID HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	29498	START UP HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	30104	MON 76669	GPP-540;	SN-SOLUTION	C+R
	32209	POWERMAX HERBICIDE	GPP-540;	SN-SOLUTION	C+R
	32356	ROUNDUP CUSTOM FOR AQUATIC AND TERRESTRIAL USE	GPI-;	SN-SOLUTION	R

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
		LIQUID HERBICIDE			
NEWAGCO INC	29290	MPOWER GLYPHOSATE	GPI-356;	SN-SOLUTION	C
NUFARM AGRICULTURE INC.	30870	GLYKAMBA HERBICIDE	GPI-194; DIC-46;	SN-SOLUTION	C
	25866	NUFARM CREDIT LIQUID HERBICIDE	GPI-356;	SN-SOLUTION	C
	27950	CREDIT PLUS LIQUID HERBICIDE	GPI-360;	SN-SOLUTION	C
	29124	CREDIT 45 HERBICIDE	GPI-450;	SN-SOLUTION	C
	29125	NUFARM CREDIT 360 LIQUID HERBICIDE	GPI-360;	SN-SOLUTION	C
	29470	NUGLO HERBICIDE	GPI-450;	SN-SOLUTION	C
	29479	POLARIS	GPI-360;	SN-SOLUTION	C
	29480	NUFARM GLYPHOSATE 360 HERBICIDE	GPI-360;	SN-SOLUTION	C
	29888	CREDIT XTREME HERBICIDE	GPO-540;	SN-SOLUTION	C
	31316	CARNIVAL 540 HERBICIDE	GPO-540;	SN-SOLUTION	C
PRODUCTIERRA	31063	SMOKE 41% GLYPHOSATE	GPI-360;	SN-SOLUTION	C
RACK PETROLEUM LTD.	30442	THE RACK GLYPHOSATE	GPI-360;	SN-SOLUTION	C
	31314	RACKETEER	GPI-360;	SN-SOLUTION	C
SHARDA CROPCHEM LIMITED	31493	SHARDA GLYPHOSATE 360	GPI-360;	SN-SOLUTION	C
	32122	GLYFO SILVI HERBICIDE	GPI-360;	SN-SOLUTION	C+R
SYNGENTA CANADA INC.	29341	HALEX GT HERBICIDE	MER-25; GPP-250; AME-250;	SN-SOLUTION	C
	29552	TAKKLE HERBICIDE	GPI-140; DIC-70;	SN-SOLUTION	C
	30412	FLEXSTAR GT HERBICIDE	GPM-271; FOF-67;	SN-SOLUTION	C
	28802	CYCLE HERBICIDE	GPP-500;	SN-SOLUTION	C
	31711	CALLISTO GT HERBICIDE	MER-45.5; GPP-455;	SU-SUSPENSION	C
	27192	TOUCHDOWN IQ LIQUID HERBICIDE	GPM-360;	SN-SOLUTION	C+R
	28072	TOUCHDOWN TOTAL HERBICIDE	GPP-500;	SN-SOLUTION	C+R
	29201	TRAXION HERBICIDE	GPP-500;	SN-SOLUTION	C+R
TERAGRO INC	29022	WEED-MASTER GLYPHOSATE 41 HERBICIDE	GPS-356;	SN-SOLUTION	C
	29009	WEED-MASTER GLYPHOSATE FORESTRY HERBICIDE	GPI-356;	SN-SOLUTION	C+R
UNITED PHOSPHORUS INC.	30366	GLYPHO 41 HERBICIDE	GPI-356;	SN-SOLUTION	C+R
UNIVAR CANADA LTD.	32228	GUARDSMAN GLYPHOSATE	GPO-540;	SN-SOLUTION	C
DOW AGROSCIENCES CANADA INC.	27351	GLYPHOSATE 18% HERBICIDE SOLUTION CONCENTRATE	GPI-143;	SN-SOLUTION	D

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
	27352	GLYPHOSATE 0.96% HERBICIDE READY-TO-USE	GPI-7;	SN-SOLUTION	D
FMC CORPORATION	26609	GLYFOS HERBICIDE 143 CONCENTRATE	GPI-143;	SN-SOLUTION	D
	26610	GLYFOS HERBICIDE 7 READY-TO-USE	GPI-7;	SN-SOLUTION	D
	26827	GLYFOS CONCENTRATE 356 HERBICIDE	GPI-356;	SN-SOLUTION	D
MONSANTO CANADA INC.	22627	ROUNDUP CONCENTRATE NON-SELECTIVE HERBICIDE	GPI-143;	SN-SOLUTION	D
	22759	ROUNDUP SUPER CONCENTRATE GRASS & WEED CONTROL	GPI-356;	SN-SOLUTION	D
	22807	ROUNDUP READY TO USE NON-SELECTIVE HERBICIDE WITH FASTACT FOAM	GPI-7;	SN-SOLUTION	D
	24299	ROUNDUP READY-TO-USE GRASS & WEED CONTROL WITH FASTACT FOAM	GPI-7;	SN-SOLUTION	D
	26263	ROUNDUP READY-TO-USE WITH FASTACT FOAM PULL'N SPRAY NON-SELECTIVE HERBICIDE	GPI-7;	SN-SOLUTION	D
	27460	ROUNDUP READY-TO-USE NON-SELECTIVE HERBICIDE	GPI-7.2;	SN-SOLUTION	D
	27506	ROUNDUP READY-TO-USE PULL'N SPRAY NON-SELECTIVE HERBICIDE	GPI-14.0;	SN-SOLUTION	D
	27507	ROUNDUP READY-TO-USE PULL'N SPRAY TOUGH BRUSH & POISON IVY CONTROL NON-SELECTIVE HERBICIDE	GPI-14.0;	SN-SOLUTION	D
	28974	ROUNDUP PUMP 'N GO	GPI-7;	SN-SOLUTION	D
	29003	ROUNDUP READY-TO-USE POISON IVY & BRUSH CONTROL NON-SELECTIVE HERBICIDE	GPI-14;	SN-SOLUTION	D
	29034	ROUNDUP READY-TO-USE POISON IVY & BRUSH CONTROL WITH QUICK CONNECT SPRAYER	GPI-14;	SN-SOLUTION	D
	31153	REFILL FOR ROUNDUP READY-TO-USE WITH WAND APPLICATOR	GPI-7.0;	SN-SOLUTION	D
	31154	ROUNDUP READY-TO-USE WITH WAND APPLICATOR	GPI-7.0;	SN-SOLUTION	D
	31514	ROUNDUP READY-TO-USE REFILL	GPI-7;	SN-SOLUTION	D

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
	31997	ROUNDUP READY-TO-USE TOUGH BRUSH & POISON IVY CONTROL WITH WAND APPLICATOR	GPI-14.0;	SN-SOLUTION	D
	32041	REFILL FOR ROUNDUP READY-TO-USE TOUGH BRUSH & POISON IVY CONTROL WITH WAND APPLICATOR	GPI-14;	SN-SOLUTION	D
	23786	ROUNDUP QUIK STIK NON-SELECTIVE HERBICIDE TABLETS	GPS-60;	TA-TABLET	D
LES PRODUITS DE CONTROLE SUPERIEUR INC/SUPERIOR CONTROL PRODUCTS INC	28464	TOTALEX CONCENTRATE BRUSH, GRASS & WEED KILLER HOME GARDENER	GPI-143;	SN-SOLUTION	D
	28467	BYEBYE WEED CONCENTRATE BRUSH, GRASS & WEED KILLER	GPI-143;	SN-SOLUTION	D
	28469	BYEBYE WEED READY-TO-USE BRUSH, GRASS & WEED KILLER	GPI-7;	SN-SOLUTION	D
	28470	TOTALEX READY-TO-USE BRUSH, GRASS & WEED KILLER HOME GARDENER	GPI-7;	SN-SOLUTION	D
	28471	TOTALEX SUPER CONCENTRATE BRUSH, GRASS & WEED KILLER HOME GARDENER	GPI-356;	SN-SOLUTION	D
	28472	BYEBYE WEED SUPER CONCENTRATE BRUSH, GRASS & WEED KILLER	GPI-356;	SN-SOLUTION	D
	28574	TOTALEX RTU BRUSH, GRASS & WEED KILLER WITH 1 TOUCH POWER SPRAYER HOME	GPI-7.0;	SN-SOLUTION	D
	28575	BYEBYE WEED RTU BRUSH, GRASS & WEED KILLER WITH 1 TOUCH POWER SPRAYER	GPI-7.0;	SN-SOLUTION	D
	28576	TOTALEX EXTRA STRENGTH RTU BRUSH, GRASS & WEED KILLER WITH 1 TOUCH POWER SPRAYER HOME GARDENER	GPI-14;	SN-SOLUTION	D
	28577	TOTALEX EXTRA STRENGTH RTU BRUSH, GRASS & WEED KILLER WITH 1 TOUCH POWER	GPI-14;	SN-SOLUTION	D

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
		SPRAYER VIRTERRA			
SURE-GRO IP INC.	27013	WILSON TOTAL WIPEOUT MAX GRASS & WEED KILLER READY TO USE	GPI-7;	SN-SOLUTION	D
	27014	WILSON TOTAL WIPEOUT MAX GRASS & WEED KILLER CONCENTRATE	GPI-143;	SN-SOLUTION	D
	27015	LATER'S GRASS & WEED KILLER SUPER CONCENTRATE	GPI-356;	SN-SOLUTION	D
	29580	WILSON TOTAL WIPEOUT MAX GRASS & WEED KILLER READY TO USE BATTERY POWERED	GPI-7;	SN-SOLUTION	D
	31023	SMARTONES WIPEOUT MAX	GPI-7.0;	SN-SOLUTION	D
	32090	WILSON TOTAL WIPEOUT MAX GRASS & WEED KILLER REFILL	GPI-7;	SN-SOLUTION	D
DOW AGROSCIENCES CANADA INC.	26449	GLYPHOSATE 62% SOLUTION MANUFACTURING CONCENTRATE	GPI-46;	SN-SOLUTION	M
	27074	VANTAGE HERBICIDE SOLUTION MANUFACTURING CONCENTRATE	GPI-356;	SN-SOLUTION	M
	27075	VANTAGE PLUS HERBICIDE SOLUTION MANUFACTURING CONCENTRATE	GPI-360;	SN-SOLUTION	M
	28963	GLYPHOSATE 85% MANUFACTURING CONCENTRATE	GPS-85;	SN-SOLUTION	M
	28783	GF-1667 HERBICIDE MANUFACTURING CONCENTRATE	GPX-49;	SN-SOLUTION	M
FMC CORPORATION	25600	GLYPHOSATE CONCENTRATE HERBICIDE	GPI-46.3;	SN-SOLUTION	M
	27497	GLYFOS 356 MUC	GPI-356;	SN-SOLUTION	M
MONSANTO CANADA INC.	21061	MON 0139 SOLUTION HERBICIDE MANUFACTURING CONCENTRATE	GPI-46.0;	SN-SOLUTION	M
	26919	MON 77945 HERBICIDE MANUFACTURING CONCENTRATE SOLUTION	GPI-46;	SN-SOLUTION	M
	28625	MON 78087 HERBICIDE MANUFACTURING CONCENTRATE	GPI-356;	SN-SOLUTION	M
	32273	GLY 135EA HERBICIDE MANUFACTURING CONCENTRATE	GPI-45.6;	SN-SOLUTION	M

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
	27485	MON 78623 HERBICIDE MANUFACTURING CONCENTRATE	GPP-47.3;	SN-SOLUTION	M
	28603	MON 79380 HERBICIDE MANUFACTURING CONCENTRATE	GPP-540;	SN-SOLUTION	M
	28604	MON 79582 HERBICIDE MANUFACTURING CONCENTRATE	GPP-540;	SN-SOLUTION	M
	28605	MON 79544 HERBICIDE MANUFACTURING CONCENTRATE	GPP-540;	SN-SOLUTION	M
	27183	MON 77973 HERBICIDE MANUFACTURING CONCENTRATE	GPS-85;	SN-SOLUTION	M
NUA	29123	NUFARM GLYPHOSATE IPA MANUFACTURING CONCENTRATE	GPI-46;	SN-SOLUTION	M
SYNGENTA CANADA INC.	27871	GLYPHOSATE 600 SL MANUFACTURING CONCENTRATE	GPS-600;	SN-SOLUTION	M
WMW	29719	TERAGRO GLYPHOSATE MANUFACTURING CONCENTRATE	GPI-46;	SN-SOLUTION	M
ALBAUGH LLC	28321	CLEAROUT GLYPHOSATE TECHNICAL	GPS-94.8;	SO-SOLID	T
AGROMARKETING CO. INC.	29645	NASA GLYPHOSATE TECHNICAL	GPS-96.37;	SO-SOLID	T
CONSUS CHEMICALS, LLC.	31728	CONSUS GLYPHOSATE TECHNICAL	GPS-96.7;	SO-SOLID	T
DOW AGROSCIENCES CANADA INC.	26450	GLYPHOSATE TECHNICAL HERBICIDE	GPS-96.3;	SO-SOLID	T
	28967	TECHNICAL GLYPHOSATE HERBICIDE	GPS-96.2;	SO-SOLID	T
FMC CORPORATION	24337	GLYPHOSATE TECHNICAL	GPS-85.8;	SO-SOLID	T
	29143	GLYFOS SOLUBLE CONCENTRATE HERBICIDE 2	GPS-97.9;	SO-SOLID	T
	29326	CHEMINOVA GLYPHOSATE TECHNICAL II	GPS-95.7;	SO-SOLID	T
	29530	CHEMINOVA GLYPHOSATE TECHNICAL III	GPS-98.2;	SO-SOLID	T
JOINT GLYPHOSATE TASK FORCE, LLC	30638	JOINT GLYPHOSATE TECHNICAL	GPS-96.3;	SO-SOLID	T
LIBERTAS NOW INC.	29265	KNOCKOUT TECH	GPS-98.1;	SO-SOLID	T
MEY CORPORATION	29799	MEY CORP GLYPHOSATE TECHNICAL	GPS-98.5;	SO-SOLID	T
	30099	MGT GLYPHOSATE TECHNICAL	GPS-96.4;	SO-SOLID	T
	30617	MEY GLYPHOSATE SHANRG TECHNICAL	GPS-97.59;	SO-SOLID	T

Registrant Name	Registration Number	Product Name	Guarantee[1] (g a.e./L)	Formulation	Marketing Class[2]
MONSANTO CANADA INC.	19535	GLYPHOSATE TECHNICAL GRADE	GPS-96.3;	SO-SOLID	T
NEWAGCO INC	29381	NEWAGCO GLYPHOSATE TECHNICAL	GPS-96.0;	SO-SOLID	T
NUFARM AGRICULTURE INC.	28857	NUFARM GLYPHOSATE TECHNICAL ACID	GPS-96.5;	SO-SOLID	T
PRODUCTIERRA	31062	PRODUCTIERRA GLYPHOSATE TECHNICAL	GPS-98.0;	SO-SOLID	T
SHARDA CROPCHEM LIMITED	29980	SHARDA GLYPHOSATE TECHNICAL HERBICIDE	GPS-96.2;	SO-SOLID	T
SYNGENTA CANADA INC.	28983	TECHNICAL TOUCHDOWN HERBICIDE	GPS-97.1;	SO-SOLID	T
	29540	TOUCHDOWN TECHNICAL HERBICIDE	GPS-99;	SO-SOLID	T
UPI GLYPHOSATE TECHNICAL HERBICIDE	30634	UPI GLYPHOSATE TECHNICAL HERBICIDE	GPS-97.7;	SO-SOLID	T
TERAGRO INC	28882	GLYPHOSATE TECHNICAL HERBICIDE	GPS-97.5;	SO-SOLID	T

[1] GPS = glyphosate acid, GPI = glyphosate isopropylamine or ethnolamine salt, GPM = glyphosate mono-ammonium or diammonium salt, GPP = glyphosate potassium salt, GPX = glyphosate dimethylsulfonium salt, and GPO = GPI + GPP. Note that GPT (glyphosate trimethylsulfonium salt) has been voluntarily discontinued by the registrant Syngenta Canada Inc.

[2] C = Commercial Class, C+R = Commercial and Restricted Class, D = Domestic Class, M = Manufacturing Concentrate, T = Technical grade active ingredient.

[3] AME = s-metolachlor, DIC = dicamba, DIQ = diquat, DXB = 2,4-D (isomer specific), FOF = fomesafen, GLG = glufosinate ammonium and MER = mesotrione.

Appendix III Summary of Species sensitivity Distribution Toxicity Data

Table 1 Revised summary of Species Sensitivity Distribution (SSDs) toxicity data analysis for glyphosate herbicide: HC_5 [1] or the most sensitive endpoints are listed by taxonomic group for Fish, Aquatic Invertebrates and Amphibians [*]

Test material	Exposure	Freshwater invertebrates (mg a.e./L)[B]	Freshwater fish (mg a.e./L)[C]	Marine fish (mg a.e./L)[C]	Marine invertebrates (mg a.e./L)[B]	Amphibians (mg a.e./L)[C]	Amphibians Mesocosm/field (mg a.e./L)[C]
TGAI	Acute	HC_5: 15.9	HC_5: 70	HC_5: 19.9	HC_5: 4.7	HC_5: 14.9	-
	Chronic	NOEC: 13.0	NOEC: 22.4	NOEC: 0.1	-	-	-
EUP NON POEA	Acute	HC_5: 24.4	HC_5: 2.3	LC_{50}: 114.6	EC_{50}: 23.2	HC_5: 13.9	-
	Chronic	EC_{50}: 44.0	-	-	-	-	-
EUP WITH POEA	Acute	HC_5: 0.1	HC_5: 2.2	HC_5: 3.0	HC_5: 0.1	HC_5: 0.73	HC_5: 3.7 HC_5: 3.3 (kg a.e/ha)
	Chronic	NOEC: 0.2	NOEC: 0.28	-	-	HC_5: 0.43	HC_5: 1.9
AMPA	Acute	LC_{50}: 316.0	LC_{50}: 274.0	-	EC_{50}: 97.0	-	-
	Chronic	-	-	-	-		-
POEA	Acute	HC_5: 0.004	HC_5: 0.2	HC_5: 2.0	EC_{50}: 0.6	HC_5: 0.3	-
	Chronic	-	-	-	-	-	-

[*]Where SSDs could not be determined, the most sensitive species endpoint value is reported; [1]Hazardous concentration to 5% of species; POEA is a formulant, POEA concentrations cannot be directly compared to other data as the concentration in a formulation varies and not specified; [B] HC_5 is derived from EC_{50} values; [C] HC_5 is derived from LC_{50} values.
TGAI = Technical grade active ingredient, EUP NON POEA = End-use product that does not contain polyethoxylated tallow amine compound in their formulation, EUP WITH POEA = End-use product that does contain polyethoxylated tallow amine compound in their formulation, AMPA = aminmethylphosphonic acid compound, POEA = polyethoxylated tallow amine

Table 2 Revised summary of Species Sensitivity Distribution (SSDs) toxicity data analysis for glyphosate herbicide: HC_5 [1] or the most sensitive endpoints are listed by taxonomic group for Aquatic Plants, Algae, Terrestrial Plants [*]

Test material	Exposure	Freshwater Algae (mg a.e./L)[B]	Freshwater Plants (mg a.e./L)	Marine Algae (mg a.e./L)	Snails (mg a.e./L)
TGAI	Acute	HC_5: 6.6 EC_{50}: 10.1	EC_{50}: 17.3 Er_{50}: 0.38 kg a.e./ha	EC_{50}: 3.35	-
	Chronic	HC_5:21.6	-	EC_{50}:101.5	NOEC: 1000
EUP NON POEA	Acute	EC_{50}: 37	-	-	-
	Chronic	-	-	-	NOEC: 29.7 NOEC: 219 (mg a.e./kg soil)
EUP WITH POEA	Acute	HC_5: 0.1	EC_{50}: 2.1	EC_{50}: 0.43	LC_{50}: 2.3
	Chronic	HC_5:0.3		EC_{50}: 8.3	NOEC: 8.55
EUP NON POEA and WITH POEA	Acute	-	-	-	-

Appendix IV Label Amendments for Products Containing Glyphosate

The label amendments presented below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

A) Label Amendments for Glyphosate Technical Products

The following label amendments are required on the Glyphosate Technical labels:

1) Add to the primary panel of the Technical product labels:

   The signal words "DANGER – EYE IRRITANT", and accompanying glyphs.

2) Before **STORAGE section, Add** the title **"ENVIRONMENTAL HAZARDS"** and the following statement:

   - **TOXIC** to non-target terrestrial plants
   - **TOXIC** to aquatic organisms

3) **Remove** the following statement under the **"DISPOSAL AND DECONTAMINATION"**

   "Canadian formulators of this technical should dispose of unwanted active and containers in accordance with municipal or provincial regulations. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in the case of a spill, and for clean-up of spills."

   and replace it with the following statement:

   "Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean up of spills, contact the manufacturer or the provincial regulatory agency."

B) For Domestic Products Containing Glyphosate

For all end-use products, the following statement is required:

"Glyphosate is not to be applied using hand-wicking or hand-daubing methods."

C) For Commercial and Agricultural Class Products Containing Glyphosate

1) Add to DIRECTIONS FOR USE:

For all end-use products, the following statement is required:

"Glyphosate is not to be applied using hand-wicking or hand-daubing methods."

Restricted Entry Intervals

"The restricted entry interval is 12 hours after application for all agricultural uses."

2) **Add to Use Precautions**

"Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

3) **Add the following to ENVIRONMENTAL HAZARDS:**

- **TOXIC** to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.
- To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil or clay.
- Avoid application when heavy rain is forecast.
- Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

4) **Add to DIRECTIONS FOR USE**

The following statement is required for all agricultural and commercial pesticide products:

- **As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests**
- **DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.**

5) Add to **DIRECTIONS FOR USE**

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

Airblast or mist blower application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side. For airblast applications, turn off outward pointing nozzles at row ends and outer rows.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment, inter-row hooded sprayer, low-clearance hooded or shielded sprayers that ensure spray drift does not come in contact with orchard crop fruit or foliage, soil drench and soil incorporation.

For application to rights-of-way and for forestry uses, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (for example, wind direction, low wind speed) and spray equipment (for example, coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands) and sensitive aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, wetlands and estuarine/marine water bodies).

Table 1 Buffer Zones for the Protection of Aquatic and Terrestrial Habitats from Spray Drift of Glyphosate Products Formulated with POEA

Agricultural, forestry and non-cropland systems		Maximum number of applications	Buffer Zones (metres) Required for the Protection of:	
			Aquatic habitats	Terrestrial habitats
Agricultural crop system and ground boom application method				
Rye, cranberry, pasture, summer fallow, all other crops for pre-seeding treatments only, filberts or hazelnut at pre-seeding only, ginseng new garden		1	1	1
Ginseng - existing established garden, Canola – Roundup Ready hybrid for seed production		2	1	1
Filberts or hazelnut, sugar beets (glyphosate tolerant varieties)		4	1	1
Corn (glyphosate non-tolerant varieties including grain, silage and ornamental types), sugar beet (glyphosate non-tolerant varieties), strawberry, blueberry highbush and lowbush, walnut, chestnut, Japanese heartnut, Turf grass (prior to establishment or renovation)		2	1	2
Wheat, barley, oats, soybean (glyphosate non-tolerant varieties), corn-sweet (glyphosate tolerant varieties), canola (glyphosate non-tolerant varieties), peas, dry beans, flax (including low linoleic acid varieties), lentils, chickpea, lupin (dried), fava bean (dried), mustard (yellow/white, brown, oriental), pearl millet, sorghum (grain) (not for use as a forage crop), asparagus, corn (glyphosate tolerant varieties), forage grasses and legume including seed production		3	1	2
Canola (glyphosate tolerant varieties), soybean (glyphosate tolerant varieties)		4	1	2
Apple, apricot, cherry (sweet/sour), peaches, pears, plums, grapes		3	1	3
Agricultural crop system and airblast application method (including mist blower)				
Pasture		1	20	30
Turfgrass (Prior to establishment or renovation)		2	25	35
Forest plant system and ground boom application method				
Forest and woodlands > 500 ha Site preparation		2	1	NR
Forest plant system and airblast application method (including mist blower)				
Forest and woodlands > 500 ha Site preparation		2	1	NR
Non-cropland system and ground boom application method				
Non-crop land and industrial uses: Industrial and rights of way areas, Recreational and public areas		3	1	3*
Non-cropland system and airblast application method (including mist blower)				
Non-crop land and industrial uses: Industrial and rights of way areas, Recreational and public areas		3	1	30*
Agricultural crop system and aerial application method	**Wing type**			
Rye, corn (glyphosate non-tolerant varieties), corn-sweet (glyphosate tolerant varieties), chickpea, lupin (dried), fava bean (dried), mustard (yellow/white, brown, oriental), pearl millet , sorghum (grain) (not for use as a forage crop), sugar beet (glyphosate non-tolerant varieties), all other crops for pre-seeding treatments only	Fixed and rotary wing	1	15	20

Agricultural, forestry and non-cropland systems		Maximum number of applications	Buffer Zones (metres) Required for the Protection of:	
			Aquatic habitats	Terrestrial habitats
Canola (glyphosate tolerant varieties)	Fixed and rotary wing	3	20	40
Sugar beets (glyphosate tolerant varieties)	Fixed wing	2	20	30
	Rotary wing	2	15	30
Wheat, barley, oats, soybean (glyphosate non-tolerant varieties), canola (glyphosate non-tolerant varieties), peas, dry beans, flax (including low linoleic acid varieties), lentils	Fixed wing	2	20	35
	Rotary wing	2	20	30
Forage grasses and legume including seed production	Fixed and rotary wing	1	20	40
Soybean (glyphosate tolerant varieties)	Fixed wing	3	20	45
	Rotary wing	3	20	40
Summer fallow	Fixed wing	1	20	45
	Rotary wing	1	20	40
Corn (glyphosate tolerant varieties)	Fixed wing	2	20	50
	Rotary wing	2	20	45
Pasture	Fixed wing	1	30	70
	Rotary wing	1	30	55
Forestry system and aerial application method				
Forest and woodlands >500 ha Site preparation	Fixed wing	2	10	NR
	Rotary wing	2	1	NR
Forest and woodlands <500 ha Site preparation	Fixed wing	2	5	NR
	Rotary wing	2	1	NR
Non-cropland system and aerial application method				
Non-crop land and industrial uses: rights-of way areas only	Fixed wing	3	100	NR
	Rotary wing	3	60	NR

* Buffer zones for the protection of terrestrial habitats are not required for forestry uses or for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.
NR = Buffer zones for the protection of terrestrial habitats are not required for forestry uses.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

Table 2 Buffer Zones for the Protection of Aquatic and Terrestrial Habitats from Spray Drift of Glyphosate Products without POEA

Agricultural and non-cropland systems		Maximum number of applications	Buffer Zones (metres) Required for the Protection of:	
			Aquatic habitats	Terrestrial habitats
Agricultural crop system and ground boom application method				
Rye, cranberry, pasture, summer fallow, pasture, all other crops for pre-seeding treatments only, filberts or hazelnut pre-seeding only, ginseng new garden		1	1	1
Ginseng - existing established garden, Canola – Roundup Ready hybrid for seed production		2	1	1
Filberts or hazelnut, sugar beets (glyphosate tolerant varieties)		4	1	1
Corn (glyphosate non-tolerant varieties including grain, silage and ornamental types), sugar beet (glyphosate non-tolerant varieties), strawberry, blueberry highbush and lowbush, walnut, chestnut, Japanese heartnut, Turf grass (prior to establishment or renovation)		2	1	2
Wheat, barley, oats, soybean (glyphosate non-tolerant varieties), corn-sweet (glyphosate tolerant varieties), canola (glyphosate non-tolerant varieties), peas, dry beans, flax (including low linoleic acid varieties), lentils, chickpea, lupin (dried), fava bean (dried), mustard (yellow/white, brown, oriental), pearl millet, sorghum (grain) (not for use as a forage crop), asparagus, corn (glyphosate tolerant varieties), forage grasses and legume including seed production		3	1	2
Canola (glyphosate tolerant varieties), soybean (glyphosate tolerant varieties)		4	1	2
Apple, apricot, cherry (sweet/sour), peaches, pears, plums, grapes		3	1	3
Agricultural crop system and airblast application method (including mist blower)				
Pasture		1	20	30
Turfgrass (Prior to establishment or renovation)		2	25	35
Non-cropland system and ground boom application method				
Non-crop land and industrial uses: Industrial and rights of way areas, Recreational and public areas		3	1	3
Non-cropland system and airblast application method (including mist blower)				
Non-crop land and industrial uses: Industrial and rights of way areas, Recreational and public areas		3	20	30
Agricultural crop system and aerial application method				
Rye, corn (glyphosate non-tolerant varieties), corn-sweet (glyphosate tolerant varieties), chickpea, lupin (dried), fava bean (dried), mustard (yellow/white, brown, oriental), pearl millet , sorghum (grain) (not for use as a forage crop), sugar beet (glyphosate non-tolerant varieties), all other crops for pre-seeding treatments only	Fixed and rotary wing	1	15	20

Agricultural and non-cropland systems		Maximum number of applications	Buffer Zones (metres) Required for the Protection of:	
			Aquatic habitats	Terrestrial habitats
Sugar beets (glyphosate tolerant varieties)	Fixed wing	2	20	30
	Rotary wing	2	15	30
Wheat, barley, oats, soybean (glyphosate non-tolerant varieties), canola (glyphosate non-tolerant varieties), peas, dry beans, flax (including low linoleic acid varieties), lentils	Fixed wing	2	20	35
	Rotary wing	2	20	30
Forage grasses and legume including seed production	Fixed and rotary wing	1	20	40
Canola (glyphosate tolerant varieties)	Fixed and rotary wing	3	20	40
Soybean (glyphosate tolerant varieties)	Fixed wing	3	20	45
	Rotary wing	3	20	40
Summer fallow	Fixed wing	1	20	45
	Rotary wing	1	20	40
Corn (glyphosate tolerant varieties)	Fixed wing	2	20	50
	Rotary wing	2	20	45
Pasture	Fixed wing	1	30	70
	Rotary wing	1	30	55
Non-cropland system and aerial application method				
Non-crop land and industrial uses: rights-of way areas only	Fixed wing	3	100	NR
	Rotary wing	3	60	NR

* Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.
NR = Buffer zones for the protection of terrestrial habitats are not required for forestry uses.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

References

Studies and Information Considered in Relation to Human Health Risk Assessment

Toxicology

A. List of Additional Studies/Information submitted by Registrant – Unpublished

PMRA Document Number	Reference
1644044	2007, Surfactant 8184-92, acute dermal toxicity study in rabbits, DACO: 4.6.2
1644045	2007, Surfactant 8184-92, acute dermal toxicity study in rats, DACO: 4.6.2
1817835	2007, Surfactant, 8184-92, acute inhalation toxicity study in rats, DACO: 4.6.3
1817836	2007, Surfactant, 8184-92, skin sensitization study in guinea pigs, DACO: 4.6.6
1817838	2007, Surfactant, 8184-92, acute eye irritation study in rabbits, DACO: 4.6.4
1817839	2008, Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats for experimental surfactant 8184-92, DACO: 4.7.7
1817840	2007, Surfactant 8184-92, acute oral toxicity study (UDP) in rats, DACO: 4.6.5
1817841	2007, Surfactant 8184-92, acute dermal irritation study in rabbits, DACO: 4.6.
2550453	2008, An 8 week oral (diet and gavage) toxicity study of citric acid in male rats, DACO: 4.8
2550454	2009, Citric Citrate 7 day palatability report, DACO: 4.8

B. List of Additional Studies/Information obtained from Published Scientific Literature Reference

Acquavella JF, Alexander BH, Mandel JS, Gustin C, Baker B, Chapman P, and Bleeke M. 2004. Glyphosate biomonitoring for farmers and their families: results from the Farm Family Exposure Study. Environmental Health Perspectives. 112(3):321-326.

Acquavella JF, Garabrant D, Marsh G, Sorahan T, and Weed DL. 2016. Glyphosate epidemiology expert panel review: a weight of evidence systematic review of the relationship between glyphosate exposure and non-Hodgkin's lymphoma or multiple myeloma. Critical Reviews in Toxicology, 46:sup1, 28-43.

Adam A, Marzuki A, Abdul Rahman H, and Abdul Aziz M. 1997. The oral and intratracheal toxicities of Roundup and its components to rats. Vet Human Toxicology. 39: 147-51.

Anadon A, Martinez-Larranaga MR, Martinez MA, Castellano VJ, Martinez M, Martin MT, Nozal MJ, and Bernal JL. 2009. Toxicokinetics of glyphosate and its metabolite aminomethyl phosphonic acid in rats. Toxicology Letters. 190: 91-95.

Antoniou M, Habib MEM, Howard CV, Jennings RC, Leifert C, Nodari RO, Robinson CJ, and Fagan J. 2012. Teratogenic effects of glyphosate-based herbicides: divergence of regulatory decisions from scientific evidence. Journal of Environmental and Analytical Toxicology. S4:006.

Antoniou, M. 2011. Roundup and birth defects: Is the public being kept in the dark? 52 pages.

APVMA (Australian Pesticide and Veterinary Medicines Authority). 2016. Glyphosate. Information about glyphosate use. Available online from http://apvma.gov.au/node/13891 [last accessed June, 2016]

Aris A, and Leblanc S. 2011. Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships in Quebec, Canada. Reproductive Toxicology. 31: 528-533.

Arbuckle, T. E., Lin, S. and Mery, L. S. 2001. An explanatory analysis of the effect of pesticide exposure on the risk of spontaneous abortion in an Ontario farm population. Environmental Health Perspectives. 109 (3): 851-857.

Astiz M, de Alaniz MJT, and Marra CA. 2009. The impact of simultaneous intoxication with agrochemicals on the antioxidant defense system in rat. Pesticide Biochemistry and Physiology 94:93-99.

BfR (Bundesinstitut für Risikobewertung). 2016. Popular misconceptions, opinions and questions in connection with BfR risk assessment of glyphosate. BfR Communication No 013/2016, 19 May 2016. Available at: http://www.bfr.bund.de/cm/349/popular-misconceptions-opinions-and-questions-in-connection-with-the-bfr-risk-assessment-of-glyphosate.pdf [last accessed June, 2016]

BfR (Bundesinstitut für Risikobewertung). 2016. Sensitive populations, especially children, are the measures of all things in scientific risk assessment. BfR Communication No 006/2016, 4 March 2016. Available at: http://www.bfr.bund.de/cm/349/sensitive-populations-especially-children-are-the-measure-of-all-things-in-scientific-risk-assessment.pdf [last accessed June, 2016]

BfR (Bundesinstitut für Risikobewertung). 2015. Glyphosate: EFSA and experts from EU Member States confirm scientific assessment of German authorities. BfR Communication No 042/2015, 12 November 2015. Available at: http://www.bfr.bund.de/cm/349/glyphosate-efsa-and-experts-from-eu-member-states-confirm-scientific-assessment-of-german-authorities.pdf [last accessed June, 2016]

BfR (Bundesinstitut für Risikobewertung). 2015. BfR review of the IARC monograph of glyphosate brought into the European assessment process. BfR Communication No 028/2015, 8 September 2015. Available at: http://www.bfr.bund.de/cm/349/bfr-review-of-the-iarc-monograph-of-glyphosate-brought-into-the-european-assessment-process.pdf [last accessed June, 2016]

BfR (Bundesinstitut für Risikobewertung). 2015. Evaluation of glyphosate contents in breast milk and urine. BfR Communication No 019/2015, 26 June 2015. Available at: http://www.bfr.bund.de/cm/349/evaluation-of-glyphosate-contents-in-breast-milk-and-urine.pdf [last accessed June, 2016]

BfR (Bundesinstitut für Risikobewertung). 2015. Does glyphosate cause cancer? – Expert group to address diverging assessments within the WHO. BfR Communication No 016/2015, 8 June 2015. Available at: http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer-expert-group-to-address-diverging-assessments-within-the-who.pdf [last accessed June, 2016]

BfR (Bundesinstitut für Risikobewertung). 2015. Does glyphosate cause cancer? BfR Communication No 007/2015, 23 March 2015. Available at: http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf [last accessed June, 2016]

BfR (Bundesinstitut für Risikobewertung). 2015. EU active ingredient test for glyphosate: current situation and outlook. BfR Communication No 002/2015, 14 January 2015. Available at: http://www.bfr.bund.de/cm/349/eu-active-ingredient-test-for-glyphosate-current-situation-and-outlook.pdf [last accessed June, 2016]

Benachour, N., Sipahutar, H., Moslemi, S., Gasnier, C., Travert, C., and Séralini, G.E. 2007. Time- and dose-dependent effects of Roundup on human embryonic and placental cells. Archives of Environmental Contamination and Toxicology. 53(1): 126-133.

Benachour, N. and Séralini, G. 2009. Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells. Chem. Res. 22 (1), pp 97–105.
Benedetti AL, Vituri C de L, Trentin AG, Domingues MACD, and Alvarez-Silva M. 2004. The effects of sub-chronic exposure of Wistar rats to the herbicide Glyphosate-Biocarb®. Toxicology Letters. 153(2):227-232.

Beuret CJ, Zirulnik F, and Giménez MS. 2005. Effect of the herbicide glyphosate on liver lipoperoxidation in pregnant rats and their foetuses. Reproductive Toxicology. 19:501-504.

Berry CL. 2010. Relativism, regulation and the dangers of indifferent science. The Sir Roy Cameron lecture of the Royal College of Pathologists. Toxicology 267 (2010) 7-13. Available online from http://www.sciencedirect.com/science/article/pii/S0300483X09005812?np=y [Last accessed February, 2016]

Boobis AR, Doe JE, Heinrich-Hirsch B, Meek ME (Bette), Munn S, Ruchirawat M, Schlatter J, Seed J, and Vickers C. 2008. IPCS Framework for Analyzing the Relevance of a Noncancer Mode of Action for Humans. Critical Reviews in Toxicology, 38:2, 87-96. Available online from http://dx.doi.org/10.1080/10408440701749421 [last accessed February, 2016]

Bohn T, Cuhra M, Traavik T, Sanden M, Fagan J, and Primicerio R. 2014. Compositional differences in soybeans on the market: glyphosate accumulates in Roundup Ready GM soybeans. Food Chemistry. 153: 207-215.

Bolognesi C, Carrasquilla Volpi S, Solomon KR, and Marshall EJP. 2009. Biomonitoring of genotoxic risk in agricultural workers from five Columbian regions: association to occupational exposure to glyphosate. Journal of Toxicology and Environmental Health, Part A: Current issues, 72:15-16, 989-997.

Bonn D. 2005. Roundup revelation: weed killer adjuvants may boost toxicity. International Health Perspectives 13(6): A403-404.

Bradberry SM, Proudfoot AT, and Vale JA. 2004. Glyphosate poisoning. Toxicological Reviews. 23(3):159-67.

Brake DG, and Evenson DP. 2004. A generational study of glyphosate-tolerant soybeans on mouse fetal, postnatal, pubertal and adult testicular development. Food Chemical Toxicology. 42(1):29-36.

Brusick D, Aardema M, Kier L, Kirkland D, and Williams G. 2016. Genotoxicity expert panel review: weight of evidence evaluation of the genotoxicity of glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid. Critical Reviews in Toxicology, 46:sup1, 56-74.

Bus, JS. 2015. Analysis of Moms Across America report suggesting bioaccumulation of glyphosate in U.S. mother's breast milk: Implausibility based on inconsistency with available body of glyphosate animal toxicokinetic, human biomonitoring, and physic-chemical data. Regulatory Toxicology and Pharmacology. 73(3):758-64.

BVL (The German Federal Office for Consumer Protection and Food Safety). 1998. Glyphosate – Annex B-5: Toxicology and Metabolism. Available online @: http://earthopensource.org/files/pdfs/Roundup-and-birth-defects/VOLUME3-1_GLYPHOSAT_05.PDF [last accessed June 5, 2013]

Çağlar S, and Kolankaya D. 2008. The effect of sub-acute and sub-chronic exposure of rats to the glyphosate-based herbicide Roundup. Environmental Toxicology Pharmacology. 25(1):57-62.

Cattani D, Cavalli VLLO, Heinz Rieg CE, Domingues JT, Dal-Cim T, Tasca CI, Mena Barreto Silva FR, and Zamoner A. 2014. Mechanisms underlying the neurotoxicity induced by glyphosate-based herbicide in immature rat hippocampus: involvement in glutamate excitotoxicity. Toxicology. 320: 34-45.

Cavalli VLLO, Cattani D, Heinz Rieg CE, Pierozan P, Zanatta L, Parisotto EB, Filho DW, Mena Barreto Silva FR, Pessoa-Pureur R, and Zamoner A. 2013. Roundup disrupts male reproductive functions by triggering calcium-mediated cell death in rat testis and Sertoli cells. Free Radical Biology and Medicine. 65: 335–346.

Chang CB, and Chang CC. 2009. Refractory cardiopulmonary failure after glyphosate surfactant

intoxication: a case report. Journal of Occupational Medicine Toxicology. 4:2.

Clair É, Mesnage R, Travert C, and Séralini GÉ. 2012. A glyphosate-based herbicide induces necrosis and apoptosis in mature rat testicular cells in vitro, and testosterone decrease at lower levels. Toxicology in Vitro. 26(2):269-279.

Dai P, Hu P, Tang J, Li Y, and Li C. 2016. Effect of glyphosate on reproductive organs in male rat. Acta Histochemica. In Press. Available online from http://www.sciencedirect.com/science/article/pii/S006512811630099X [last accessed June, 2016]

Dallegrave E, Mantese FD, Coelho RS, Pereira JD, Dalsenter PR, and Langeloh A. 2003. The teratogenic potential of the herbicide glyphosate-Roundup in Wistar rats. Toxicology Letters. 142:45-52.

Dallegrave E, Mantese FD, Oliveira RT, Andrade AJM, Dalsenter PR, and Langeloh A. 2007. Pre- and postnatal toxicity of the commercial glyphosate formulation in Wistar rats. Archives of Toxicology. 81 (9): 665-673.

Daruich J, Zirulnick F, and Giménez MS. 2001. Effect of the herbicide glyphosate on enzymatic activity in pregnant rats and their foetuses. Environmental Research. 85:226-231.

Defarge N, Takacs E, Lozano VL, Mesnage R, Vendômois, SD, Seralini GE, and Szekacs A. 2016. Co-formulants in glyphosate-based herbicides disrupt aromatase activity in human cells below toxic levels. International Journal of Environmental Research and Public Health. 13(3). Available online from http://www.mdpi.com/1660-4601/13/3/264 [last accessed June, 2016]

De Araujo JS, Delgado IF, and Paumgartten FJ. 2016. Glyphosate and adverse pregnancy outcomes, a systemic review of observational studies.

De Roos AJ, Zahm SH, Cantor KP, Weisenburger DD, Holmes FF, Burmeister LF, and Blair A. 2003. Integrative Assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men. Occupational & Environmental Medicine. 60 (11).

De Roos AJ, Blair A, Rusiecki AA, Hoppin JA, Svec M, Dosemeci M, Sandler DP, and Alavanja MC. 2004. Cancer incidence among glyphosate-exposed pesticide applicators in the Agricultural Health Study. Environmental Health Perspectives, 113(1): 49-54.

De Roos AJ, Svec MA, Blair A, Rusiecki JA, Dosemeci M, Alavanja MC, Hoppin JA, and Sandler, DP. 2005. Glyphosate results revisited: De Roos et al., respond. Environmental Health Perspectives 113, A366–A367.

Dietert RR. The Microbiome in early life: self-completion and microbiota protection as health priorities. Birth Defects Research (Part B) 101: 333-340 (2014). Available online from http://onlinelibrary.wiley.com/doi/10.1002/bdrb.21116/abstract [last accessed June, 2016]

Elie-Caille C, Heu C, Guyon C, and Nicod L. 2010. Morphological damages of a glyphosate-treated keratinocyte cell line revealed by a micro- to nanoscale microscopic investigation. Cell

Biology and Toxicology. 26: 331-339.

El-Shenawy NS. 2009. Oxidative stress responses of rats exposed to Roundup and its active ingredient glyphosate. Environmental Toxicology Pharmacology. 28(3):379-385.

Eriksson M, Hardell L, Carberg M, and Akerman M. 2008. Pesticide exposure as risk factor for non-Hodgkin lymphoma including histopathological subgroup analysis. International Journal of Cancer. 123: 1657-63.

ECHA (European Chemicals Agency). 2016. Public consultation on the harmonised classification and labelling proposal for Glyphosate. ECHA/NI/16/25. 2016. Available online from http://echa.europa.eu/view-article/-/journal_content/title/public-consultation-on-the-harmonised-classification-and-labelling-proposal-for-glyphosate [last accessed June, 2016]

EC (European Commission). 2002. Review report for the active substance glyphosate, Directive 6511/VI/99-final. 21 January 2002. Available online from http://ec.europa.eu/food/plant/protection/evaluation/existactive/list1_glyphosate_en.pdf [Last accessed June 7, 2013]

EFSA (European Food Safety Authority). 2011. Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Scientific Committee, EFSA journal, 9, 2379.

EFSA (European Food Safety Authority). 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015; 13(11):4302 [107 pp.] Available online from: https://www.efsa.europa.eu/en/efsajournal/pub/4302 [Last accessed June, 2016]

EFSA (European Food Safety Authority), 2015a. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance glyphosate.

EFSA (European Food Safety Authority). 2015. Statement of EFSA on the request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine. EFSA Journal 2015; 13(11):4303, 13 pp. doi:10.2903/j.efsa.2015.4303. Available online from: http://www.efsa.europa.eu/en/efsajournal/pub/4303 [Last accessed February, 2016]

EFSA (European Food Safety Authority). 2015. EFSA explains the carcinogenicity assessment of glyphosate. Available online from: http://www.efsa.europa.eu/en/topics/factsheets/glyphosate151112 [last accessed June, 2016]

EFSA (European Food Safety Authority). 2016. Glyphosate: EFSA responds to critics. Available online from http://www.efsa.europa.eu/en/press/news/160113 [last accessed June, 2016]

EFSA (European Food Safety Authority). 2015. Glyphosate: background documents published. Available online from http://www.efsa.europa.eu/en/press/news/151119a [last accessed June, 2016]

EFSA (European Food Safety Authority). 2015. Glyphosate: EFSA updates toxicological profile.

Available online from http://www.efsa.europa.eu/en/press/news/151112 [last accessed June, 2016]

EPA (U.S. Environmental Protection Agency). 2012. Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment. Available online from http://www2.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf [last accessed February, 2016]

EPA (U.S. Environmental Protection Agency). 2010. February 2010 FIFRA SAP meeting minutes: Draft Framework and Case studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment. Available online from https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0125-0079 [last accessed February, 2016]

EPA (U.S. Environmental Protection Agency). 1986. Guidelines for mutagenicity risk assessment. Fed. Register 51. 34006-34012.

EPA (U.S. Environmental Protection Agency). 2010. February 2010 FIFRA SAP meeting minutes: Draft Framework and Case studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment. Available online from https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0125-0079 [last accessed February, 2016]

EPA (U.S. Environmental Protection Agency). 2015. Cancer Assessment Document – Evaluation of the Carcinogenic Potential of Glyphosate. Final Report. Cancer Assessment Review Committee. Available online from http://src.bna.com/eAi [Last accessed June, 2016]

EPA (U.S. Environmental Protection Agency). 2001. General Principles for Performing Aggregate Exposure and Risk Assessments. Available online from http://www2.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf [Last accessed February, 2016]

EPA (U.S. Environmental Protection Agency). 2015. Glyphosate: Weight of Evidence Analysis of Potential Interaction with the Estrogen, Androgen, or Thyroid Pathways. Available online from https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0361-0047 [last accessed February, 2016]

EPA (U.S. Environmental Protection Agency). 2010. Phosphate ester, tallowamine, ethoxylated. Human health risk assessment to support proposed exemption from the requirement of a tolerance when used as inert ingredients in pesticide formulations.

EPA (U.S Environmental Protection Agency). 2006. Memorandum - Glyphosate human health risk assessment for proposed use on Indian mulberry and amended use on pea, dry.

EPA (U.S. Environmental Protection Agency). 1993. Reregistration Eligibility Decision (RED). Glyphosate.

EPA (U.S. Environmental Protection Agency). 2009. Glyphosate. Human health Assessment

Scoping Document in Support of Registration Review.

EPA (U.S. Environmental Protection Agency). 2016. FIFRA Scientific Advisory Panel Meetings. Carcinogenic Potential of Glyphosate. Docket Number: EPA-HQ-OPP-2016-0385

FDA (U.S. Food and Drug Administration). 2012. Guidance for Industry. S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use. Available online from http://www.fda.gov/downloads/Drugs/Guidances/ucm074931.pdf [last accessed February, 2016]

FDA (U.S Food and Drug Administration). 2012. Guidance for Industry – Immunotoxicology Evaluation of Investigational New Drugs. Available online from http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079239.pdf [last accessed June, 2016]

Food Safety Commission of Japan. 2016. Glyphosate Summary. Food Safety, 4(3): 93-102. Available online form https://www.jstage.jst.go.jp/article/foodsafetyfscj/4/3/4_2016014s/_pdf [last accessed October, 2016]

Gasnier C, Dumont C, Benachour N, Clair E, Chagnon M, and Seralini GE. 2009. Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines. Toxicology. 262(3):184-191.

Gasnier C, Benachour N, Clair E, Travert C, Langlois F, Laurent C, Decroix-Laporte C, and Seralini GE. 2010. Dig 1 protects against cell death provoked by glyphosate-based herbicides in human liver cell lines. Journal of Occupational Medicine and Toxicology. 5:29.

Gehin A, Guillaume YC, Millet J, Guyon C, and Nicod L. 2005. Vitamins C and E reverse effect of herbicide-induced toxicity on human epidermal cells HaCaT: a biochemometric approach. International Journal of Pharmaceutics. 288(2):219-226.

George J, Prasad S, Mahmood Z, and Shukla Y. 2010. Studies on glyphosate-induced carcinogenicity in mouse skin: a proteomic approach. Journal of Proteomics. 73(5):951-964.

Goldstein DA, Farmer DL, Levine SL, and Garnett RP. 2005. Mechanism of Toxicity of Commercial Glyphosate Formulations: How Important is the Surfactant? Journal of Toxicology: Clinical Toxicology, 43(5):423-424.

Germany, 1998. Draft assessment report (DAR) on the active substance glyphosate prepared by the rapporteur Member State Germany in the framework of Directive No 91/414/EEC, December 1998. Available at www.efsa.europa.eu

Germany, 2013. Renewal assessment report (RAR) on the active substance glyphosate prepared by the rapporteur Member State Germany in the framework of Regulation (EU) No 1141/2010, December 2013. Available at www.efsa.europa.eu

Germany, 2015. Final Addendum to the renewal assessment report on glyphosate, compiled by EFSA, October 2015. Available at www.efsa.europa.eu

Greim H, Saltmiras D, Mostert V, and Strupp C. 2015. Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies. Critical Reviews of Toxicology. 45(3): 185-208. Available online from http://dx.doi.org/10.3109/10408444.2014.1003423 [last accessed June, 2016]

Harris SB, and DeSesso JM, 1994. Practical guidance for evaluating and interpreting developmental toxicity tests. Journal of Hazardous Materials, 39: 245-266.

Heydens WF, Healy CE, Hotz KJ, Kier LD, Martens MA, Wilson AGE, and Farmer DR. 2008. Genotoxic potential of glyphosate formulations: mode-of-action investigations. Journal of Agriculture and Food Chemistry. 56(4):1517-1523.

Hernandez-Plata I, Giordano M, Diaz-Munoz M, and Rodriguez VM. 2015. The herbicide glyphosate causes behavioral changes and alterations in dopaminergic markers in male Sprague-Dawley rat. Neurotoxicology. 46:79-91. Available online from http://www.sciencedirect.com/science/article/pii/S0161813X14002162 [last accessed, June 2016]

Hokanson R, Fudge R, Chowdhary R, and Busbee D. 2007. Alteration of estrogen-regulated gene expression in human cells induced by the agricultural and horticultural herbicide glyphosate. Human & Experimental Toxicology. 26(9):747-752.

Hultberg M. 2007. Cysteine turnover in human cell lines is influenced by glyphosate. Environmental Toxicology and Pharmacology. 24(1):19-22.

Jayasumana C, Gunatilake S, and Senanayake P. 2014. Glyphosate, hard water and nephrotoxic metals: are they the culprits behind the epidemic of chronic kidney disease of unknown etiology in Sri Lanka? International Journal of Environmental Research and Public Health. 11: 2125-2147.

IARC (International Agency for Research on Cancer). 2015. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 112. Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos. Available online from http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf [last accessed June, 2016]

IARC (International Agency for Research on Cancer). 2015. Preamble, IARC monograph –112. Available on online from http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-F06.pdf [last accessed February, 2016]

IARC (International Agency for Research on Cancer). 2015. Note to the Reader, IARC monograph –112. http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-F04.pdf

Kier LD, and Kirkland DJ. 2013. Review of genotoxicity biomonitoring studies of glyphosate and glyphosate-based formulations. Critical Reviews of Toxicology. 43(4): 283-315. Available online from http://www.tandfonline.com/doi/full/10.3109/10408444.2013.770820 [last accessed June, 2016]

Kier LD. 2015. Review of genotoxicity biomonitoring studies of glyphosate-based formulations. Critical Reviews of Toxicology. 45(3): 209-218. Available online from http://www.tandfonline.com/doi/full/10.3109/10408444.2015.1010194 [last accessed June, 2016]

Kimmel GL, Kimmel CA, Williams AL, DeSesso JM. 2013. Evaluation of developmental toxicity studies of glyphosate with attention to cardiovascular development. Critical Reviews in Toxicology, 43 (2): 79-95.

Krüger M, Schledorn P, Schrödl W, Hoppe HW, Lutz W, and Shehata AA. 2014. Detection of glyphosate residues in animals and humans. Environmental & Analytical Toxicology 4(2):1-5.

Landgren O, Kyle RA, Hoppin JA, Freeman LEB, Cerhan JR, Katzmann JA, Alavanja MC. 2009. Pesticide exposure and risk of monoclonal gammopathy of undetermined significance in the Agricultural Health Study. Blood, 113(25), 6386-6391.

Lee HL, Chen KW, Chi CH, Huang JJ, and Tsai LM. 2000. Clinical Presentations and Prognostic Factors of a Glyphosate — Surfactant Herbicide Intoxication: A Review of 131 Cases. Academic Emergency Medicine. 7(8):906-10.

Lee CH, Shih CP, Hsu KH, Hung DZ, and Lin CC. 2008. The early prognostic factors of glyphosate-surfactant intoxication. American Journal of Emergency Medicine 26(3): 275-281.

Lee HL and Guo HR. 2011. The Hemodynamic Effects of the Formulation of Glyphosate-Surfactant Herbicides. Herbicides, Theory and Applications. Prof. M Larramendy (Ed.) ISBN, 978-953.

Levine SL, Han Z, Liu J, Farmer DR, and Papadouplous V. 2007. Disrupting mitochondrial function with surfactants inhibits MA-10 Leydig cell steroidogenesis. Cell Biology and Toxicology, 23, 385–400. Available online from http://link.springer.com/article/10.1007%2Fs10565-007-9001-6 [last accessed June, 2016]

Li AP, and Long TJ. 1987. An evaluation of the genotoxic potential of glyphosate. Fundamental and Applied Toxicology 10:537-546. Institute of Environmental Toxicology, Tokyo.

Malhotra RC, Ghia, DK, Cordato DJ, and Beran RG. 2010. Glyphosate-surfactant herbicide-induced reversible encephalopathy. Journal of Clinical Neuroscience. 17:1472-1473.

Manas F, Peralta L, Raviolo J, Garcıa Ovando H, Weyers A, Ugnia L, GonzalezCid M, Larripa, I, and Gorla N. 2009. Genotoxicity of AMPA, the environmental metabolite of glyphosate, assessed by the Comet assay and cytogenetic tests. Ecotoxicology and Environmental Safety. 72: 834-837.

Marc J, Mulner-Lorillon O, and Bellé R. 2004. Glyphosate-based pesticides affect cell cycle regulation. Biology of the Cell. 96(3):245-249.

McClellan, RO. 2016. Evaluating the potential carcinogenic hazard of glyphosate. Critical Reviews in Toxicology, 46:sup1, 1-2.

McDuffe HH, Pahwa P, McLaughlin JR, Spinelli JJ, Fincham S, Dosman JA, Robson D, Skinnider LF, and Choi NW. 2001. Non-Hodgkin's lymphoma and specific pesticide exposure in men: cross-Canada study of pesticides and health. Cancer Epidemiology, Biomarkers, & Prevention. 10: 1155-63.

McQueen H, Callan AC, and Hinwood AL. 2012. Estimating maternal and prenatal exposure to glyphosate in the community setting. International Journal of Hygiene and Environmental Health, 215(6):570-576.

McGuire MK, McGuire MA, Price Wj, Shafi B, Carrothers JM, Lackey KA, Goldstein DA, Jensen PK, and Vicini JL. 2016. Glyphosate and aminomethylphosphonic acid are not detectable in human milk. The American Journal of Clinical Nutrition. 103(5):1285-90. Available online from: http://ajcn.nutrition.org/content/103/5/1285.long [Last accessed June, 2016]

Mesnage R, Bernay B, and Seralini GE. 2013. Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity. Toxicology. 313: 122-128.

Mesnage R, Defarge N, Vendômois J, and Seralini GE. 2014. Major pesticides are more toxic to human cells than their declared active principles. Biomed Research International. Volume 2014 (2014), Article ID 179691, 8 pages.

Mesnage R, Defarge N, Vendômois J, and Seralini GE. 2015. Potential toxic effects of glyphosate and its commercial formulations below regulatory limits. Food and chemical toxicology. 84:133-53. Available online from http://www.sciencedirect.com/science/article/pii/S027869151530034X [last accessed June, 2016]

Mesnage R, Renney G, Seralini GE, Ward M, and Antoniou MN. 2017. Multiomics reveal non-alcoholic fatty liver disease in rats following chronic exposure to an ultra-low dose of Roundup herbicide. Scientific Reports 7, article number: 39328.

Mink PJ, Mandel JS, Lundin JI, and Sceurman BK, 2011. Epidemiologic studies of glyphosate and non-cancer health outcomes: a review. Regulatory Toxicology and Pharmacology. 61:172-184.

Mladinic M, Berend S, Vrdoljak AL, Kopjar N, Radic B, and Zeljezic D. 2009. Evaluation of genome damage and its relation to oxidative stress induced by glyphosate in human lymphocytes in vitro. Environmental and Molecular Mutagenesis. 50(9): 800-807.

Moorman AFM, and Christoffels VM, 2003. Cardiac Chamber Formation: Development, Genes, and Evolution. Physiology Reviews. 83: 1223-1267. Available online @ http://physrev.physiology.org/content/83/4/1223.full [Last accessed July 10, 2013]

Mose T, Kjaerstad MB, Mathiesen L, Nielsen JB, Edelfors S, and Knudsen LE. 2008. Placental passage of benzoic acid, caffeine, and glyphosate in an ex vivo human perfusion system. Journal of Toxicology and Environmental Health, Part A. 71(15):984-991.

NTP (National Toxicology Program). 1992. Technical Report on Toxicity Studies of Glyphosate

Administered in Dosed Feed to F344/N Rats and B6C3F1 Mice. Glyphosate, NTP Toxicity Report Number 16.

Ntzani EE, Chondrogiorgi M, Ntritsos G, Evangelou E, and Tzoulaki I. 2013. Literature review on epidemiological studies linking exposure to pesticides and health effects. EFSA (European Food Safety Authority), EFSA supporting publication 2013:EN-497, 159 pp. Available online from http://www.efsa.europa.eu/en/supporting/pub/497e [Last accessed February, 2016]

NZEPA (New Zealand Environmental Protection Authority). Review of the Evidence Relating to Glyphosate and Carcinogenicity. 2016. Available online from http://www.epa.govt.nz/Publications/EPA_glyphosate_review.pdf [last accessed August, 2016]

OECD, Organisation for Economic Co-operation and Development (OECD). 2012, Adverse Outcome Pathways, Molecular Screening and Toxicogenomincs. Available online from http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm [Last accessed February, 2016]

OECD (Organisation for Economic Co-operation and Development). 1997, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1. OECD Principles on Good Laboratory Practice (as revised in 1997). Available online from http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/mc/chem(98)17&doclanguage=en [Last accessed June, 2016]

Paganelli A, Gnazzo V, Acosta H, Lopez SL, and Carrasco AE. 2010. Glyphosate-based herbicides produce teratogenic effects on vertebrates by impairing retinoic acid signaling. Chemical Research in Toxicology. 23: 1586-1595.

Peixoto F. 2005. Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation. Chemosphere 61:1115-1122.

Pesticides residues in food. 2016. Special Session of the Joint FAO/WHO Meeting on Pesticide Residues – Report 2016. ISSN 2070-2515. FAO Plant Production and Protection Paper 227. Available online from http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/ [last accessed June, 2016]

Pesticide residues in food. 2004. Joint FAO/WHO Meeting on Pesticides Residues – Evaluations 2004 Part II - Toxicological.

Pieniazek D, Burkowska B, and Duda W. 2004. Comparison of the effect of Roundup Ultra 360 SL pesticide and its active compound glyphosate on human erythrocytes. Pesticide Biochemistry and Physiology. 79:58-63.

PMRA (Pest Management Regulatory Agency). 2003. General Principles for Performing Aggregate Exposure and Risk Assessments. Available online from http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2003-04-eng.pdf [Last accessed February, 2016]

PMRA (Pest Management Regulatory Agency). 2001. Science Policy Notice (SPN2001-01)

Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment. Available online from http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2001-01-eng.pdf [Last accessed June, 2016]

PMRA (Pest Management Regulatory Agency). 2015. Pest Management Regulatory Agency's Approach to Assessing Cumulative Effects of Pesticides. Available online from http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/pesticide-safety-securite-pesticide/effects-pesticides-effets-eng.php [Last accessed June, 2016]

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 June, 2016]

PMRA (Pest Management Regulatory Agency). 2005. Regulatory Directive (DIR2005-01) Guidelines for Developing a Toxicological Database for Chemical Pest Control Products. Available online from http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2005-01/index-eng.php [Last accessed June, 2016]

PMRA (Pest Management Regulatory Agency). 2005. Regulatory Note: PMRA List of Formulants. Available online from http://publications.gc.ca/collections/Collection/H113-7-2005-1E.pdf [Last accessed February, 2016]

PMRA (Pest Management Regulatory Agency). 2006. Regulatory Directive: Formulants Policy and Implementation Guidance Document. Available online from http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2006-02-eng.pdf [Last accessed February, 2016]

Potti A, and Seghal I. 2005. Exposure to pesticides increases levels of uPA and uPAR in pre-malignant human prostate cells. Environmental Toxicology Pharmacology. 19(2): 215-219.

Prasad S, Srivasta S, Singh M, and Shukla Y. 2009. Clastogenic effects of glyphosate in bone marrow cells of Swiss albino mice. Journal of Toxicology. 2009: 6 pages.

Rank J, Jensen AG, Skov B, Pendersen LH, and Jensen K. 1993. Genotoxicity testing of the herbicide Roundup and its active ingredient glyphosate isopropylamine using the mouse bone marrow micronucleus test, Salmonella mutagenicity test, and Allium anaphase-telophase test. Mutation Research. 300:29-36.

Richard S, Moslemi S, Sipahutar H, Benachour N, and Seralini GE. 2005. Differential effects of glyphosate and Roundup on human placental cells and aromatase. Environmental Health Perspectives. 113(6): 716-720.

Roberts DM, Buckley NA, Mohamed F, Eddleston M, Goldstein DA, Mehrsheikh A, Bleeke MS, and Dawson AH. 2010. A prospective observational study of the clinical toxicology of glyphosate-containing herbicides in adults with acute self-poisoning. Clinical Toxicology, 48(2):129-136.

Romano RM, Romano MA, Bernardi MM, Furtado PV, and Oliveira CA. 2010. Prepubertal exposure to commercial formulation of the herbicide glyphosate alters testosterone levels and testicular morphology. Archives of Toxicology. 84(4):309-317.

Romano MA. 2012. Glyphosate impairs male offspring reproductive development by disrupting gonadotropin expression. Archives of Toxicology. 86:663-673.

Samsel A, and Seneff S. 2013. Glyphosate's suppression of Cytochrome P450 enzymes and amino acid biosynthesis by the gut microbiome: pathways to modern diseases. Entropy. 15: 1416-1463.

Samsel A, and Seneff S. 2013. Glyphosate, pathways to modern diseases II: Celiac sprue and gluten intolerance. Interdisciplinary Toxicology. 6(4) : 159-184.

Samsel A, and Seneff S. 2015. Glyphosate, pathways to modern diseases III: Manganese, neurological diseases, and associated pathologies. Surgical Neurology International. 6 (45).

Schinasi L, and Leon ME. 2014. Non-Hodgkin lymphoma and occupational exposure to agricultural pesticide chemical groups and active ingredients: a systematic review and meta-analysis. International Journal of Environmental Research and Public Health 11: 4449-4527.

Seneff S, Swanson NL, and Li C. 2015. Aluminum and glyphosate can synergistically induce pineal gland pathology: connection to gut dysbiosis and neurological disease. Agricultural Sciences, 6, 42-70

Seralini GE, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, Spiroux de Vendômois J. 2013. Answers to critics: why there is a long-term toxicity due to a roundup-tolerant genetically modified maize and to a Roundup herbicide. Food and Chemical Toxicology. 53:461-468.

Seralini GE, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, Spiroux de Vendômois J. 2014. Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Environmental Sciences Europe. 26: 14.

Seralini GE, Mesnage R, Gress S, Defarge N, Spiroux de Vendômois J. 2014. Conclusiveness of toxicity and double standards. Food and Chemical Toxicology. 69: 357-359.

Shehata AA, Shrödl W, Aldin AA, Hafez HM, Kürger M. 2013. The effect of glyphosate on potential pathogens and beneficial members of poultry microbiota in vitro. Current Microbiology 66(4): 350-358. Available online from http://link.springer.com/article/10.1007%2Fs00284-012-0277-2 [Last accessed June, 2016]

Solecki R, Pfeil R, Sieke C, and Niemann L. 2015. A critical review of glyphosate findings in human urine samples and comparison with the exposure of operators and consumers. Journal of Consumer Protection and Food Safety, BfR. 10:3-12. Available online from http://rd.springer.com/article/10.1007/s00003-014-0927-3 [Last accessed June, 2016]

Sorahan T. 2015. Multiple Myeloma and Glyphosate Use: A Re-Analysis of US Agricultural

Health Study (AHS) Data. International Journal of Environmental Research and Public Health, 12, 1548-1559.

Solomon KR. 2016. Glyphosate in the general population and in applicators: a critical review of studies on exposure, Critical Reviews in Toxicology, 46:sup1, 21-27.

Stabler J, Kessedjian MJ, and Perraud J. (1983). Use of the New Zealand White rabbit in teratology: Incidence of spontaneous and drug-induced malformations. Food Chemistry & Toxicology. 21 (5): 631-636

Steinborn A, Alder L, Michalski B, Zomer P, Bendig P, Martinez SA, Mol HG, Class TJ, and Pinheiro NC. Determination of glyphosate levels in breast milk samples from Germany by LC-MS/MS and GC-MS/MS. Journal of Agricultural and Food Chemistry. Available online from http://pubs.acs.org/doi/abs/10.1021/acs.jafc.5b05852 [last accessed June, 2016]

Stella J. and Ryan M. 2004. Herbicide formulation: A potentially lethal ingestion. Emergency Medicine Australasia. 16: 235-239.

Stump DG, Nemerc MD, and Parker GA. (2006). Significance, reliability and interpretation of developmental and reproductive toxicity study findings. In: Hood RD, ed. Developmental and reproductive toxicology: a practical approach. 2nd ed. Chap 9. New York: Taylor and Francis Group, 329-424

Swanson NL, Leu A, Abrahamson J, and Wallet B. 2014. Genetically engineered crops, glyphosate and the deterioration of health in the United States of America. Journal of Organic Systems, 9(2).

Talbot AR, Shiaw MH, Huang JS, Yang SF, Goo TS, Wang SH, and Sanford TR. 1991. Acute poisoning with a glyphosate-surfactant herbicide ('roundup'): a review of 93 cases. Human and Experimental Toxicology. 10(1):1-8.

Thakur DS, Khot R, Joshi PP, Pandharipande M, and Nagpure K. 2014. Glyphosate poisoning with acute pulmonary edema. Toxicology International. 21(3): 328-30. Available online from http://www.ncbi.nlm.nih.gov/pubmed/25948977 [last accessed June, 2016]

Thongprakaisang S, Thiantanawat A, Rangkadilok N, Suriyo T, Satayavivad J. 2013. Glyphosate induces human breast cancer cells growth via estrogen receptors. Food Chemistry & Toxicology. 59 129-136.

Vasiluk L, Pinto LJ, and Moore MM. 2005. Oral bioavailability of glyphosate: studies using two intestinal cell lines. Environmental Toxicology and Chemistry. 24(1):153-160.

Walsh LP, McCormick C, Martin C, and Stocco DM. 2000. Roundup Inhibits Steroidogenesis by Disrupting Steroidogenic Acute Regulatory (StAR) Protein Expression. Environ Health Perspective. 108(8): 769–776.

Wang G, Fan XN, Tan YY, Cheng Q, and Chen SD. 2011. Parkinsonism after chronic occupational exposure to glyphosate. Parkinsonism & Related Disorders. 17(6):486-487.

Williams GM, Kroes R, and Munro, IC. 1999. Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans. Regulatory Toxicology and Pharmacology. 31(2): 117-165.

Williams AL, Watson RE, and DeSesso JM. 2012. Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis. Journal of Toxicology and Environmental Health, Part B: Critical Reviews. 15:1, 39-96

Williams GM, Aardema M, Acquavella J, Berry C, Brusick D, Burns MD, Camargo JLV, Garabrant D, Greim H, Larry KD, Kirkland DJ, Marsh G, Solomon KR, Tom Sorahan T, Ashley R, and Weed DL. 2016. A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment. Critical Reviews in Toxicology, 46:sup1, 3-20

Williams GM, Berry C, Burns M, Camargo JLV, and Greim H. 2016. Glyphosate rodent carcinogenicity bioassay expert panel review. Critical Reviews in Toxicology, 46:sup1, 44-55.

World Health Organization. 2005. Glyphosate and AMPA in drinking water. Background document for development of WHO Guidelines for Drinking-water Quality. WHO/SDE/WSH/03.04/97.

WHO (World Health Organization – International Programme on Chemical Safety), 2012. Guidance for Immunotoxicity Risk Assessment for Chemicals. Available online from http://www.inchem.org/documents/harmproj/harmproj/harmproj10.pdf [Last accessed June, 2016]

Wu JY, Chang SS, Tseng CP, Deng JF, and Lee CC. 2006. Parenteral glyphosate-surfactant herbicide intoxication. The American Journal of Emergency Medicine. 24(4):504-6.

Yeung F. 2010. Heart Embryology. Cardiac Embryology Website. Toronto General Hospital Department of Anesthesia Perioperative Interactive Education. Available online at: http://pie.med.utoronto.ca/htbg/HTBG_content/assets/applications/index.html [last accessed June 12, 2013]

Dietary Exposure

List of Additional Studies/Information obtained from Published Scientific Literature

International Programme on Chemical Safety (IPCS). 1999. Environmental Health Criteria 210. Next link will take you to another Web site Principles for the Assessment of Risks to Human Health from Exposure to Chemicals. Geneva, Switzerland, World Health Organization, International Programme on Chemical Safety. www.inchem.org/documents/ehc/ehc/ehc210.htm

Studies and Information Considered in Relation to the Environmental Risk Assessment

List of Additional Studies/Information obtained from Published Scientific Literature

Antoniou, M. 2011. Roundup and birth defects: Is the public being kept in the dark? Earth Open Source: 1-52. http://earthopensource.org/earth-open-source-reports/roundup-and-birth-defects-is-the-public-being-kept-in-the-dark/

Annett, R. Habibi, H.R. and Hotela, A. 2014. Impact of glyphosate and glyphosate-based herbicides on the freshwater environment. J. Appl. Toxicology 34:458-479. PMRA 2460749

Babendreier, D., Reichhart, B., Romeis, J. and Bigler, F. 2008. Impact of insecticidal proteins expressed in transgenic plants on bumblebee microcolonies. Entomologia Experimentalis et Applicata 126: 148–157.

Battaglin, W.A., Kolpin, D.W., Scribner, E.A., Kuivila, K.M. and Sandstrom, M.W. 2005, Glyphosate, other herbicides, and transformation products in Midwestern streams, 2002. PMRA 2423832.

Battaglin, W.A., Meyer, M.T., Kuivila, K.M. and Dietze, J.E. 2014. Glyphosate and its degradation product AMPA occur frequently and widely in US soils, surface water, groundwater and precipitation. Journal of the American Water resources Association. 50 (2): 275-290.

Battaglin, W.A. and Kolok, A. 2014. Featured collection introduction: contaminants of emerging concern II. Journal of the American Water resources Association. 50 (2): 261-265.

Bernard, M.B., Cole, P., Kobelt, A., Horne, P.A., Altmann, J., Wratten, S.D and Yen, A.L., 2010, Reducing the impact of pesticides on biological control in australian vineyards: pesticide mortality and fecundity effects on an indicator species, the predatory mite *euseius victoriensis* (acari: *phytoseiidae*) - Journal of Economic Entomology, Volume 103, Number 6, Pages 2061 to 2071. PMRA 2462245.

Bhowmik, P.C. 1994. Biology and control of common milkweed (*Asclepias syriaca*). Reviews in Weed Science 6: 227-250.

Bonnineau, C., Gallard Sague, I. Urrea, G. and Guasch, H. 2012. Light history modulates antioxidant and photosynthetic responses of biofilms to both natural (light) and chemical (herbicides) stressors - Ecotoxicology, Volume 21: 1208-1224. PMRA 2462244.

Borggaard, O.K. andGimsing, A.L. 2008. Fate of glyphosate in soil and the possibility of leaching to ground and surface waters: a review. Pest Manag. Sci. 64:441-456.

Brower, L.P., Taylor, O.R., Williams, E.H., Slayback, D.A., Zubieta, R.R. and Ramírez, M.I. 2012. Decline of monarch butterflies overwintering in Mexico: is the migratory phenomenon at risk? Insect Conservation and Diversity 5: 95-100.

Capri, E. and Vicari, A. 2010. Environmental fate and behaviour of glyphosate and its main metabolite. European Glyphosate Environmental Information Source (Egeis). PMRA 2460735

Carpenter, J. and Gianessi, L. (1999) Herbicide tolerant soybeans: why growers are adopting Roundup Ready varieties. AgBioForum 2(2): 65-72.

Chang, F.C., Simcik, M.F. and Capel, P.D. 2011. Occurrence and fate of the herbicide glyphosate and its degradate aminomethylphosphonic acid in the atmosphere. Environmental Toxicology and Chemistry, 30 (3): 548-555. PMRA 2459642.

Coupe, R.H., Kalkhoff, S.J., Capel, P.D. andGregoire, C., 2011, Fate and transport of glyphosate and aminomethylphosphonic acid in surface waters of agricultural basins - Pest Management Science, 68: 16-30. PMRA 2460748.

de Jonge, H., de Jonge, L.W., Jacobsen, O.H., Yamaguchi, T. and Moldrup, P. 2001. Glyphosate sorption in soils of different pH and phosphorus content. Soil Science, 166 (4): 230-238. PMRA 2459651.

Doll, J. 1998. How weeds have changed over 20 years. Proceedings of the Wisconsin Fertilizer, AgLime, and Pest Management Conference 37: 144-147. http://fyi.uwex.edu/weedsci/1998/11/12/how-weeds-have-changed-over-20-years/.

Duan, J.J., Marvier, M., Huesing, J., Dively, G. and Huang, Z.Y. 2008. A meta-analysis of effects of Bt crops on honey bees (Hymenoptera: Apidae). PLoS ONE 3 (1): e1415. doi: 10.1371/journal.pone.0001415.

Duke, S.O and Powles, S.B. 2008. Mini-review; Glyphosate: a once-in-a-century herbicide. Pest Management Science, 64: 319-325.

Edwards, W.M., Triplett, G.B., Kramer, R.M., 1980, A watershed study of glyphosate transport in runoff - Journal of Environmental Quality, Volume 9, Pages 661 to 665. PMRA 2462226.

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302

Fairchild, W.L. Brown, S.B. and Moore, A. 2002. Effects of freshwater contaminants on marine survival in Atlantic salmon. NPAFC Tech Report No. 4.

Farenhorst, A., McQueen, D.A.R., Saiyed, I., Hildebrand, C., Li, S., Lobb, D.A., Messing, P., Schumacher, T.E., Papiernik, S.K. and Lindstrom, M.J. 2009. Variations in soil properties and herbicide sorption coefficients with depth in relation to PRZM (pesticide root zone model) calculations. Geoderma, 150 (3-4): 267-277.

Fernandez, M.R., Zentner, R.P., Basnyat, P., Gehl, D., Selles, F. and Huber, D. 2009. Glyphosate associations with cereal diseases caused by *Fusarium* spp. in the Canadian Prairies. Europ. Journ. of Agrol. 31:133-143.

Foreman, W.T., Majewski, M.S., Goolsby, D.A., Wiebe, F.W. and Coupe, R.H. 2000. Pesticides in the atmosphere of the Mississippi river valley, part II – air. Science of the Total Environment. 248: 213-216.

Glozier, N.E., Struger, J., Cessna, A.J., Gledhill, M., Rondeau, M., Ernst, W.R., Sekela, M.A., Cagampan, S.J., Sverko, E., Murphy, C., Murray, J.L. and Donald, D.B. 2012. Occurrence of glyphosate and acidic herbicides in select urban rivers and streams in Canada, 2007. Environmental Science and Pollution Research International, 19 (3): 821-834.

Gregoire, C., Payraudeau, S. and Domange, N. 2010. Use and fate of 17 pesticides applied on a vineyard catchment. Intern J Environ Anal. Chem 90:406–420.

Hardy, B. and Desgranges, J. 1990. Évaluation des effets à moyen terme sur les communatés aviennes de l'entretien des plantations d'épinettes noires (*Picea mariana*) aux phénoxys (Estaprop) et au glyphosate (Roundup). Série de Rapports Techniques No. 101. Environment Canada, Canadian Wildlife Service.

Haughton, A.J., Bell, J.R., Wilcox, A. and Boatman, N.D.1999. The effects of different rates of the herbicide glyphosate on spiders in arable field margins. J. Arachnol. 27(1): 249-254.

Haughton, A.J., Bell, J.R., Wilcox, A. and Boatman, N.D. 2001a. The effect of the herbicide glyphosate on non-target spiders: part ii. indirect effects on *lepthyphantes tenuis* in field Margins. Pest Manag. Science (2001) 57: 1037-1042.

Haughton, A.J., Bell, J.R., Wilcox, A. and Boatman, N.D. 2001b. The effect of the herbicide glyphosate on non-target spiders: part i. direct effects on *lepthyphantes tenuis* under laboratory conditions. Pest Manag. Science (2001) 57: 1033-1036.

Helander, M., Saloniemi, I. and Saikkonen, K. 2012. Glyphosate in Northern ecosystems. Trends in Plant Science, 17 (10): 569-574.

Hendrix, P.F. and Parmelee, R.W. 1985. Decomposition, nutrient loss and microarthropod densities in herbicide-treated grass litter in a Georgia piedmont agroecosystem. Soil Biol. Biochem. 17(4): 421-428.

Hermann, P. 2001. Glyphosate: A Tier II laboratory study to evaluate the effect of a SL formulation on the staphylinid beetle, *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae). Syngenta. Performed by Arbeitsgemeinschafi GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH. Lab. Rep. 20001034/01-NEAb. 31 p. CBI. PMRA 1213232.

Hurley, T., Sadiq, R. and Mazumder, A. 2012. Adaptation and evaluation of the Canadian Council of Ministers of the Environmental Water Quality Index (CCME WQI) for use as an effective tool to characterize drinking water source water quality, Water Research, 46 (11) 3544-3552.

Jackson, R.E., Pitre, H.N. 2004. Influence of Roundup Ready Soybean Production Systems and Glyphosate Application on Pest and Beneficial Insects in Narrow-Row Soybean. J. Agric. Urban Entomol. Sci. 21 (2): 61-70.

Jadhav A,Hill M,Byrne M. 2008. Identification of a Retardant Dose of Glyphosate with Potential for Integrated Control of Water Hyacinth, Eichhornia crassipes (Mart.) Solms-Laubach. Biol. Control 47(2): 154-158

Jayasumana, C., Gunatilake, S. and Senanayake, P. 2014. Glyphosate, hard water and nephrotoxic metals: are they the culprits behind the epidemic of chronic kidney disease of unknown etiology in Sri Lanka? Int. Jour. Res. Public Health. 11: 2125-2147.

Kedwards, H.A. and Travis, A. 2001. Glyphosate: A Tier II laboratory study to evaluate the effect of SL formulation on the hoverfly *Epysyrphus balteatus* (Diptera: syrphidae). Syngenta, Berkshire, UK. Rep. Series RJ3125B. Study No. 00JH125. 24 p. CBI. PMRA 1213236.

Kramer, R.M. and Beasley, R.K. 1975. Determination of residues of glyphosate and its metabolite in Fish. Interim Report on CP 67573, Residue and metabolism. Agricultural research report No. 378. Job No. 9-23-760.06-7163. Monsanto. 39 p. **CBI document. PMRA 1182548.**

Linz, G.M., Bergman, D.L. and Bleier, W.J. 1992. Progress on managing cattail marshes with Rodeo herbicide to disperse roosting blackbirds. Proceedings of the 15th Vertebrate Pest Conference J.E. Borrecco & R.E. Marsh (editors). University of California Davis: 56-61.

Linz, G.M., Blixt, D.C., Bergman, D.L. and Bleier, W.J. 1994. Response of black terns (Chlidonias niger) to glyphosate-induced habitat alterations on wetlands. Colonial waterbirds. 17 (2): 160-167.

Linz, G.M., Bergman, D.L., Homan, J. and Bleier, W.J. 1995. Effects of herbicide-induced habitat alterations on blackbird damage to sunflower. Crop Protection, 14 (8): 625-629.

Linz, G.M., Blixt, D.C., Bergman, D.L. and Bleier, W.J. 1996a. Effects of red-winged blackbirds, yellow-headed blackbirds and marsh wrens to glyphosate-induced alterations in cattail density. Journal of Field ornithology. 67 (1): 167-176.

Linz, G.M., Blixt, D.C., Bergman, D.L. and Bleier, W.J. 1996b. Response of ducks to glyphosate-induced habitat alterations in wetlands. Wetlands, 16 (1): 38-44.

MacKinnon, D.S. and Freedman, B. 1993. Effects of sylvicultural use of the herbicide glyphosate on breeding birds of regenerating clearcuts in Nova Scotia, Canada. Journal of Applied Ecology, 30 (3): 395-406.

Majewski, M.S., Coupe, R.H., Foreman, W.T. and Capel, P.D.2014b. Pesticides in Mississippi air and rain: a comparison between 1995 and 2007. Environmental Toxicology and Chemistry, 33 (6) : 1283-1293.

Majewski, M.S., Foreman, W.T. and Goolsby, D.A. 2000. Pesticides in the atmosphere of the Mississippi river valley, part I – rain. Science of the Total Environment, 248: 201-212.

Malone, L.A. and Burgess, E.P.J. 2009. Impact of Genetically Modified Crops on Pollinators. In: Ferry N, Gatehouse AMR (Eds) Environmental impact of genetically modified crops. CAB

International (Oxfordshire, UK): 199–224.

Malone, L.A., Scott-Dupree, C.D., Todd, J.H. and Ramankutty, P. 2007. No sublethal toxicity to bumblebees, *Bombus terrestris*, exposed to Bt-corn pollen, captan and novaluron. New Zealand Journal of Crop and Horticultural Science 35: 435–439.

Mensink, H. and Janseen, P. 1994. Glyphosate; Environmental Health Criteria 159. IPCS (International Programme on Chemical Safety); World health Organization, Geneva. 81 p. PMRA 2462253

Morandin, L.A. and Winston, M.L. 2003. Effects of novel pesticides on bumble bee (Hymenoptera:Apidae) colony health and foraging ability. Environmental Entomology 32: 555–563.

Morrison, M.L. and Meslow, E.C. 1984. Response of avian communities to herbicide-induced vegetation changes. The Journal of Wildlife Management; 48 (1): 14-22.

Murray, T.E., Kuhlmann, M. and Potts, S.G. 2009. Conservation ecology of bees: populations, species and communities. Apidologie 40: 211–236.

Newton, I. 2004. The recent declines of farmland bird populations in Britain: an appraisal of causal factors and conservation actions. British ornithologist Union, Ibis, 146: 579-600.

Newton, M., Howard, K.,M., Kelpsas, B.R., Danhaus, R., Lottman, C.M., Dubelman, S, 1984, Fate of glyphosate in an Oregon forest ecosystem - Journal of Agricultural Food Chemistry, Volume 32, Pages 1144 to 1151. PMRA 1155371.

Paganelli, A., Gnazzo, V., Acosta, S., Lopez, S.L. and Carrasco, A.E. 2010. Glyphosate-based herbicides produce teratogenic effects on vertebrates by imparing retinoic acid signaling. Chem. Res. Toxicol. 23:1586-1595.

Peruzzo, P.J., Porta, A.A., Ronco, A.E. 2008. Levels of glyphosate in surface waters, sediments and soils associated with direct sowing soybean cultivation in north pampasic region of Argentina. Environmental Pollution, 156 (1) : 61-66.

Pleasants, J.M. and Oberhauser, K.S. 2012. Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population. Insect Conservation and Diversity 6(2): 135-144.

Relyea, R.A. 2005a. The Lethal Impacts of Roundup And Predatory Stress On Six Species of North American Tadpoles. Archives of Environmental Contamination and Toxicology, 48: 351-357.

Relyea, R.A. 2005b. The Impact of Insecticides and Herbicides on the Biodiversity and Productivity of Aquatic Communities. Ecol. Appl. 15(2): 618-627.

Relyea, R.A. 2005c. The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians. Ecol. Appl. 15(4): 1118-1124

Roy, D.N., Konar, S.K., Banerjee, S., Charles, D.A., Thompson, D.G., Prasad, R., 1989, Persistence, movement and degradation of glyphosate in selected Canadian Boreal forest soils - Journal of Agricultural Food Chemistry, 37: 437-440. PMRA 2460737.

Sanchis, J., Kantiani, L., Llorca, M., Rubio, F., Ginebreda, A., Fraile, J., Garrido, T., Farre, M., 2011, Determination of glyphosate in groundwater samples using an ultrasensitive immunoassay and confirmation by on-line solid-phase extraction followed by liquid chromatography coupled to tandem mass spectrometry - Analytical and Bioanalytical Chemistry, 402: 2335-2345, PMRA 2460750.

Santillo, D.J., Brown, P.W. and Leslie D.M. Jr. 1999. Response of songbirds to glyphosate-induced habitat changes on clearcuts. Journal of Wildlife Management. 53 (1): 64-71.

Santos, M.J.G., Ferreira, M.F.L., Cachada, A., Duarte, A.C., Sousa, J.P., 2012, Pesticide application to agricultural fields: effects on the reproduction and avoidance behaviour of *Folsomia candida* and *Eisenia andrei* - Ecotoxicology, 21: 2113-2122. PMRA 2469288.

Screpanti, C., Accinelli, C., Vicari, A. and Catizone, P. 2005. Glyphosate and glufosinate-ammonium runoff from a corn-growing area in Italy - Agronomy for Sustainable Development, 25: 407-412. PMRA 2460734.

Scribner, E.A., Battaglin,W.A., Gillion, R.J., Meyer, M.T. , 2007, Concentrations of glyphosate, its degradation product, aminomethylphosphonic acid, and glufosinate in ground- and surface-water, rainfall and soil samples collected in the United States 2001-06 - U.S. Geological Survey Scientific investigations Report 2007-5122. PMRA 2460747.

Sihtmae, M., Blinova, I., Kunnis-Beres, K., Karabik, L. Heinlaan, M. and Kahru, A. 2013. Ecotoxicological effects of different glyphosate formulations. Applied Soil Ecology, 72:215-224. PMRA 2574468.

Siimes, K., Ramo, S. Welling, L., Nikunen, U., Laitinen, P., 2006, Comparison of the behaviour of three herbicides in a field experiment under bare soil conditions - Agriculture Water Management, 84: 53-64. PMRA 2462224.

Sorberg, K.L. and Higgins, K.F. 1993. Effects of glyphosate herbicide on cattails, invertebrates and waterfowl in South Dakota wetlands. Wildlife Society Bulletin, 21 (3): 299-307.

Struger, J., Thompson, D., Staznik, B., Martin, P., McDaniel, T., Marvin, C., 2008, Occurrence of glyphosate in surface waters in Southern Ontario - Bulletin of Environmental Contamination and toxicology, 80: 378-384. PMRA 1739313.

Sullivan, T.P. and Sullivan, D.S. 2003. Vegetation management and ecosystem disturbance: impact of glyphosate herbicide on plant and animal diversity in terrestrial systems. Environmental Review 11: 37-59. PMRA 2469318)

Takacs, P., Martin, P.A., Struger, J., 2002. Pesticides in Ontario: A critical assessment of potential toxicity of agricultural products to wildlife, with consideration for endocrine disruption

Volume 2: Triazine herbicides, glyphosate and metolachlor - Environment Canada Technical Report Series: Number 369. PMRA 2462252.

Thompson, H.M. 2012 Interaction between pesticides and other factors in effects on bees. Supporting
Publications 2012:EN-340. [204 pp.]. Available online: www.efsa.europa.eu/publications

Thompson, H. M, Levine, S.L., Doering, J. , Norman, S., Manson, P., Sutton, P. and von Mrey, G. 2014, Evaluating exposure and potential effects on honeybee brood (*Apis mellifera*) development using glyphosate as an example - integrated Environmental Assessment and Management, Volume 10, Issue 3, Pages 463 to 470. PMRA2482648.

Vera, M.S.; Lagomarsino, L.; Sylvester, M.; Pérez, G.L.; Rodriguez, P.; Mugni, H.; Sinistro, R.; Ferraro, M.; Bonetto, C.; Zagares, H. & Pizarro, H. 2010. New evidence of Roundup (glyphosate formulation) impact on periphyton community and the water quality of freshwater ecosystems. Ecotoxicology, 19: 710-721.

Vereecken, H. 2005. Mobility and leaching of glyphosate: a review. Pest Management Science, 61: 1139-1151.

Villeneuve, J. 2012. Reconsideration of special reviews for glyphosate products. Environmental Assessment Directorate; Pest Management Regulatory Agency, Health Canada. 86 p. PMRA 2203372

Waite, D.T., Bailey, P., Sproull, J.F., Quiring, D.V., Chau, D.F., Bailey, J. and Cessna, A.J. 2005. Atmospheric concentrations and dry and wet deposits of some herbicides currently used on the Canadian Prairies. Chemosphere, 58: 693-703.

Waldecker, M.A. and Wyse, D.L. 1985. Chemical effects of the accumulation of glyphosate in common milkweed (*Asclepias syriaca*) root buds. Weed Science, 33 (5): 605-611.

Walker, H.M., Elcock, V.L. and Daft, S. 2000. Glyphosate: A Tier 1 laboratory study to evaluate the effects of a SL formulation on the carabid beetle *Poecilus cupreus* (Coleoptera: Carabidae). Zeneca. Rep. No. ER-00-HMA380, Study No. HMA 380. 32 p. CBI. PMRA 1213231.

World Health Organization (WHO). 2004. Guidelines for Drinking-water Quality. Third Edition, Volume 1. Recommendations. Geneva, Switzerland. 516 p.
https://books.google.ca/books?hl=en&lr=&id=SJ76COTmnQC&oi=fnd&pg=PR15&dq=Guidelines+for+Drinkingwater+Quality.+Third+Edition,+Volume+1.+Recommendations.+&ots=V7t_wcQb49&sig=zd13EGcuw_EKcBiGWJFMwpfcZoM#v=onepage&q=Guidelines%20for%20Drinkingwater%20Quality.%20Third%20Edition%2C%20Volume%201.%20Recommendations.&f=false

Yao, Y., Tuduri, L., Harner, T., Blanchard, P., Waite, D., Poissant, L., Murphy, C., Belzer, W., Aulagnier, F., Li, Y-F. and Sverko, E. 2006. Spatial and temporal distribution of pesticide air concentratiosn in Candian agricultural regions. Atmospheric Environment, 40: 4339-4351.

Health Canada / Santé Canada

Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la Loi sur les produits antiparasitaires

Date received – Date reçue: 2017-06-27

Submission No. - N° de la demande: 2017-3047

1. Objector Information – Information sur l'opposant

Name – Nom / Corporation – société / Organization – organisation*: Mary Lou McDonald. On my own behalf and as president of Safe Food Matters Inc.

Postal Delivery Address – Adresse de livraison postale*: 9 Boardwalk Dr. Unit 107

City / Town – Ville*	Prov / State – Province / État*	Country – Pays*	Postal Code / ZIP – Code postal / ZIP*
Toronto	ON	Canada	M4L 6T1

Phone – Téléphone*	Fax – Télécopieur	E-mail – Courriel
905 467-8531		mlmcdonald5@gmail.com

2. Product Information – Information sur le produit

Name of active ingredient to which the decision relates – Nom de la matière active à laquelle la décision se rapporte*: Glyphosate

Name of end-use product to which the decision relates – Nom de la préparation commerciale à laquelle la décision se rapporte*: All end-use products containing glyphosate as active ingredient

3. Registration decision to which the objection relates – Décision d'homologation pour laquelle vous déposez un avis d'opposition*

Decision on application – Décision concernant la demande

- [ ] Granting registration – Homologation accordée
- [ ] Denying registration – Homologation rejetée
- [ ] Granting an amendment of a registration – Modification à l'homologation accordée
- [ ] Denying an amendment of a registration – Modification à l'homologation rejetée

Decisions on re-evaluation or special review – Décision concernant la réévaluation ou l'examen spécial

- [X] Confirming registration – Homologation confirmée
- [ ] Cancelling registration – Homologation annulée
- [ ] Amending registration – Modification à une homologation

4. Date the decision statement was made public – Date de la publication de l'énoncé de décision*

April 28 2017

5. Area of scientific evaluation to which the objection relates – Volet de l'évaluation scientifique touché par l'avis d'opposition*

- [X] Health risk assessment (toxicology, food residue, occupational exposure) – Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)
- [ ] Environmental risk assessment (environmental fate, environmental toxicology) – Évaluation des risques pour l'environnement (devenir dens l'environnement, écotoxicologie)
- [ ] Value and efficacy assessments (crop tolerance, value) – Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection – Fondement scientifique de l'opposition*

Attachment included? – Pièce jointe incise? X/ Yes – Oui | No – Non

See the Notice of Objection. Glyphosate applied for desiccation purposes is placing residues in the seeds to that extent that they exceed MRLs and are of concern to human health, especially considering increased consumption of the relevant foods, and that evidence of such translocation and accumulation has not been considered in the Re-evaluation or contemplated in the law.

This is **Exhibit "B"** referred to in the Affidavit of Mary Lou McDonald affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely, this 21st day of April, 2023

Bronwyn Roe

Commissioner for Taking Affidavits
Bronwyn Roe, LSO #63840R

7. Signature of objector or representative – Signature de l'opposant ou de son représentant	Printed Name – Nom en lettres moulées*	Date*
M McDonald	Mary Lou McDonald	June 27, 2017

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

NOTICE OF OBJECTION

Hon.Jane.Philpott@Canada.ca

I, Mary Lou McDonald, in my own capacity and in my capacity as the president of Safe Food Matters Inc., am filing this Notice of Objection to the Minister of Health, the Hon. Jane Philpott, with respect to the decision on glyphosate taken in Re-evaluation Decision RVD2017-01 ("RVD2017-01"), *Glyphosate* pursuant to section 35 of the *Pest Control Products Act* (the "Act").

Introduction

Section 35 of the Act provides:

> *35 (1) Any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1)(a) or (b) within 60 days after the decision statement referred to in subsection 28(5) is made public.*

The decision taken in RVD2017-01 was taken pursuant to paragraph 28(b) of the Act and concerned the registration of glyphosate on completion of a re-evaluation. The decision ("2017 Decision") was:

> *After a re-evaluation of the herbicide glyphosate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act and Regulations, is granting continued registration of products containing glyphosate for sale and use in Canada.*
>
> *An evaluation of available scientific information found that products containing glyphosate do not present risks of concern to human health or the environment when used according to the revised label directions. As a requirement for the continued registration of glyphosate uses, new risk reduction measures are required for the end-use products registered in Canada. No additional data are being requested at this time.*

This Notice of Objection provides arguments based on science and reason objecting to the 2017-Decision. It references studies, literature and government publications. It also references policy documents of Health Canada, since the Act indicates in Section 8 that the Minister shall give effect to government policy in evaluating the health and environmental risks and the value of a pest control product.

Reason for Objection

The main basis for this objection is that glyphosate applied for desiccation purposes is placing residues in the seeds to that extent that they exceed MRLs and are of concern to human health, especially considering increased consumption of the relevant foods, and that evidence of such translocation and accumulation has not been considered in the Re-evaluation or contemplated in the law. The support for this is set out in point 1-4 below. The remaining points provide other objections.

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

The substance of these points is set out below.

1) Desiccation with Glyphosate on Crops Causes MRL Exceedances

Glyphosate is being used as a desiccant in pre-harvest applications Canada. It is sprayed on crops to kill them for purposes of harvesting. PMRA indicates glyphosate is registered as a desiccant on a number of conventional crops, including wheat, barley, oats, canola, flax, lentils, peas, drybeans and soybeans (RVD2017-01 at 38). The Saskatchewan Government's 2017 Guide to Crop Protection (at 235) indicates glyphosate can be used for "Crop Staging for Preharvest applications" (desiccation) on the conventional crops described above and on the additional crops of chickpeas, lupin, faba bean, canaryseed, camelina, mustard and forage (the **"Additional Crops"**). Desiccation is occurring on a large scale: for example, grower surveys conducted in the United States and Canada show that between 60 and 85% of dry bean acres are treated with a desiccant in any given year.[1]

The literature indicates when glyphosate is applied to crops that have already emerged, it translocates to the seeds of the plant. Moreover, the earlier glyphosate is applied as a desiccant, or the more moisture content there is in the plant, the higher the residue levels in the plant. This is because glyphosate moves preferentially to growing points, which are largely the seed. If glyphosate is applied to a crop that is not physiologically mature, it accumulates more in the seed.[2]

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[1] Dr. Jeanette Gaultier and Dr. Rob Gulden, "The science and art of dry bean desiccation" (2017) Crops and Soils 49:4 12

2 Ibid.

> "Glyphosate is a systemic product, which means that once it enters the plant it gets into the circulation system and moves through the plant to the same places that the sugars are going, which are called sinks.... The sink at pre-harvest is the seed. So basically what you are doing by applying early is taking what is applied to the surface of the leaf and putting it right into the seed."[3]

The higher levels of residue have been observed with cereals and legumes, including spring wheat, field pea, barley, flax, canola, dry beans and lentils, among other crops.[4]

The scientific literature indicates that the early application of glyphosate as a desiccant or the application of glyphosate when moisture content is too high has resulted in exceedances of the Maximum Residue Limits ("**MRLs**") for some crops: in Canada and/or countries that import the particular crop.

By way of example, the following studies had the above finding on MRL exceedances with respect to the following crops:

a) Wheat seed:

> Cessna, A. J., Darwent, A. L., Kirkland, K. J., Townley-Smith, L., Harker, K. N. and Lefkovitch, L.P. "Residues of glyphosate and its metabolite AMPA in wheat seed and foliage following preharvest applications" (1994) 74 Can. J. Plant Science 653

b) Red Lentils:

> Ti Zhang, Eric N. Johnson, Thomas C. Mueller, Christian J. Willenborg "Early Application of Harvest Aid Herbicides Adversely Impacts Lentil" (2017) 109 (1) Agronomy Journal No. 239
>
> T. Zhang, E.N. Johnson(2), S. Banniza, and C.J. Willenborg, "Evaluation of Harvest Aids Application Timing for Lentil Dry Down" (2016) 30(3) Weed Technology 629 [Zhang 2016]
>
> Ti Zhang, "Evaluation of Herbicides as Desiccants for Lentil ((Lens culinaris Medik) Production" (2015) Masters of Science Thesis University of Saskatoon [Zhang Thesis]

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3 Clark Benzil, provincial weed specialist with the Saskatchewan Ministry of Agriculture, as quoted in Angela Lovell, "Don't use desiccants to hasten maturity", Grainews (4 June 2012), online: <www.grainew.ca>

[4] Cessna, A. J., Darwent, A. L., Kirkland, K. J., Townley-Smith, L., Harker, K. N., & Lefkovitch, L. P. (1994). Residues of glyphosate and its metabolite AMPA in wheatseed and foliage following preharvest applications. Canadian Journal of Plant Science, 74(3), 653-661; Cessna, A. J., Darwent, A. L., Townley-Smith, L., Harker, K. N., & Kirkland, K. J. (2000).Residues of glyphosate and its metabolite AMPA in canola seed following preharvest applications. Canadian Journal of Plant Science, 80(2), 425-431; Cessna, A. J., Darwent, A. L., Townley-Smith, L., Harker, K. N., & Kirkland, K. (2002), Residues of glyphosate and its metabolite AMPA in field pea, barley and flax seed following preharvest applications. Canadian Journal of Plant Science, 82(2), 485-489.

c) Dry beans:

Kristen E. McNaughton, Robert E. Blackshaw, Kristine A. Waddell, Robert H. Gulden, Peter H. Sikkema,1 Chris L. Gillard, "Effect of Application Timing of Glyphosate and saflufenacil as desiccants in dry edible bean (*Phaseolus vulgaris* L)" (2015) 95(2) Canadian Journal of Plant Science 369. [McNaughton 2015]

NOTE: This study is published on the website of Agriculture and Agri-Food Canada, Science Publications and Resources, date modified 2015-05-21.

Dr. Jeanette Gaultier and Dr. Rob Gulden, "The science and art of dry bean desiccation" (2017) Crops and Soils 49:4 12

d) Field Peas:

Cessna, A. J., Darwent, A. L., Townley-Smith, L., Harker, K. N. and Kirkland, K. J. 2002, "Residues of glyphosate and its metabolite AMPA in field pea, barley and flax seed following preharvest applications" (2002) 82. Can. J. Plant Sci. 485 [Cessna 2002]

The expectation in the literature that MRL exceedances will occur with desiccated crops is being manifest in fact in Canada. There is evidence of exceedances in a cereal and legume, based on data recently obtained from the Canadian Food Inspection Agency (**"CFIA"**) pursuant to an Access to Information Request submitted by Mr. Tony Mitra.[5] The information provided by the CFIA indicated "violations" had occurred with respect to chickpeas and wheat bran. **Twenty-six out of 71 chickpea samples that were assessed, or 36.6%, were considered in violation,** and 2 out of 55 wheat bran samples were in violation.

The details of the violations are set out in Appendix I and II, attached.

Food containing a pesticide residue that does not exceed the established MRL does not pose a health risk concern according to Health Canada (PRVD2015-01 at 3). The corollary is that foods that DO exceed the established MRL DO pose a health risk.

In conclusion, the literature shows that MRLs for some crops, in particular cereals and legumes, can be exceeded when glyphosate is used as a desiccant and the crop has a high moisture content, and the CFIA data shows that exceedances in crops that have likely been desiccated is occurring. Such exceedances pose a health risk. In other words, they endanger human health.

2) **Evidence of Dietary Exposure to Glyphosate as a Desiccant Not Examined in PRVD2015-01**

[5] Tony Mitra, "Glyphosate in chickpea, lentil and wheatbran" (June 15, 2017) http://www.tonu.org/2017/06/15/glyphosate-in-chickpea-lentil-and-wheat-bran/

There is no discussion of dietary exposure through harvest management or desiccation applications of glyphosate in the content of PRVD 2015-01. All that exists is an indication (at 11) that Appendix IIa lists the Commercial Class uses for which glyphosate is "currently" registered (as at 3 May 2012). The Commercial Class uses included "harvest management" (desiccation) for the following crops: wheat, barley, oats, soybeans, soybeans (Glyphosate tolerant or Roundup Ready soybean varieties, or Roundup Ready 2 Yield soybean varieties) canola, canola (glyphosate tolerant), peas, dry beans, flax (including low linoleic acid varieties), lentils, chickpeas, lupin (dried), fava bean (dried), mustard (yellow/white, brown, oriental), pearl millet (pearl millet grain is to be harvested for use as animal feed only. Do not graze treated pearl millet forage or cut for hay.), sorghum (grain) (not for use as a forage crop), Forage grasses and legume including seed production.

Apart from the above references to "harvest management", the only other mentions of harvest management or desiccation in PVRD 2015-01 are under discussions of "value" where it is stated (at 6): "It is one of few herbicides that can also be used as harvest management and desiccation treatment" and (at 42) "The pre-harvest application of glyphosate provides additional benefits to growers as it functions both as a harvest management and a desiccation treatment". Then an explanation is provided.

Dietary exposure from desiccated crops was also not discussed in the content of Section 3.2 of the Science Evaluation forming part of PRVD2015-01 (pages 17-18) that concerned "Dietary Exposure and Risk Assessment".

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. It is submitted that such an examination is necessary, particularly given the understanding provided above of the mechanisms by which MRLs can be exceeded in desiccated crops, and that data from the CFIA indicates that exceedances are occurring in fact.

3) **Evidence that Dietary Exposure of Desiccated Crops has Increased**

Section 3.2 of the Science Evaluation forming part of PRVD2015-01 (at 17-18) concerned "Dietary Exposure and Risk Assessment". It indicated that "The PMRA Science Policy Note SPN2003-03, Assessing Exposure from Pesticides, A User's Guide" presents detailed acute, chronic and cancer-risk assessment procedures." ("**SPN2003-03**").

The risk procedures outlined in SPN2003-03 describe how exposure to a pesticide is determined (at 3):

> *"The amount of pesticide to which an individual is exposed (i.e. exposure) is determined by combining the amount of pesticide that is in or on the food (i.e. residue levels) and the amount and type of foods that people eat (i.e. food consumption)."*

With respect to food consumption, SPN2003-03 indicates (at 7):

> *"Consumption information comes from the USDA's Continuing Survey of Food Intake by Individuals (CSFII), which provides survey data of what people eat in the United States*

(U.S.).and Canada."

This food survey data from CSFII is used by the PMRA since Canadian and American eating habits have been shown to be similar if not identical (p. 8). The data from CSFII as referenced in SPN2003-03 is data from at best 2003, that date of the Science Policy Note. The actual name of CSFII, however, is 1994-1996, 1998 Continuing Survey of Food Intakes by Individuals, which means the data is from at best 1998.
Data from these sources is outdated, and consumption of desiccated crops (and hence production) of desiccated crops has increased markedly since the data date.

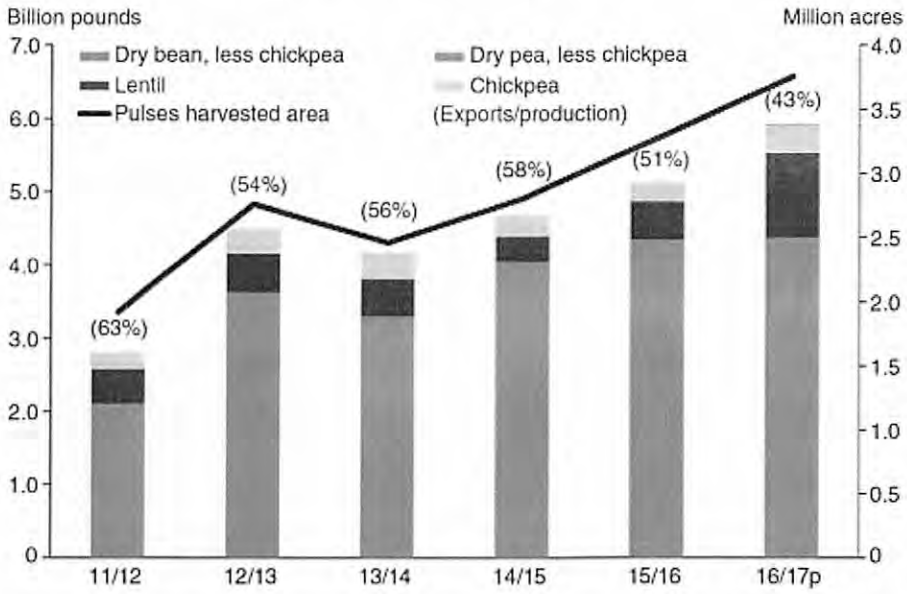
Even if more current data available to PMRA is taken into consideration, the data is still outdated and evidence on current consumption levels is needed. In Science Policy Note SPN2014-01, General Exposure Factor Inputs for Dietary, Occupational and Residential Exposure Assessments, PMRA (at 8) indicated that it was adopting the United States WWEIA (What We Eat in America) consumption data as part of DEEM-FCID, primarily due to its larger sample size and the fact that it is a continuous survey that is more representative of current eating habits. Appendix I to SPN2014-01 indicates that consumption data used in dietary exposure assessments was reviewed in 2010 and incorporated into the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID)". So the last consumption data that the PMRA currently uses, aside from the Re-evaluation is, at best, from 2010.

However this data is in sufficient for purposes of reevaluating glyphosate. The consumption of chickpeas in the United States has grown at least 90% since 2010. Hummus is a dip made form chickpeas, and over a quarter of Americans reported in 2014 that they had the dip in the refrigerators. Consumer spending on hummus has reached $1 billion a year in 2014, after growing some 18% a year over the previous five years – six times faster than the overall growth of the American food market.[6] Lentils and other leguminous crops have also trended high for several years, and lentils and chickpeas will reach record highs in the 2016/17 marketing year. [7]

Because consumption is increasing, production is as well. Below is a chart that shows the rise in production of pulses in the United States in the years since 2010.

6 Yoram Gabison, "The Dip That Roared: How Humus Conquered the US" June 20, 2014 Haaretz
7 Jennifer Bond, "Pulses Production Expanding as Consumers Cultivate a Taste for U.S. Lentils and Chickpeas" (2017) Amber Waves

U.S. pulses production and harvested area are on the rise



2016/17 production is projected. Marketing year is June 1-July 30.
Sources: USDA, Economic Research Service calculations using USDA, National Agricultural Statistics Service, QuickStats database.

Part of the reason for increased consumption is large marketing efforts. The Pulse Canada publication "2016 International Year of Pulses Final Report" (at 10) indicated "In a June 2016 survey, 36% of Canadian consumers and 49% of US consumers indicated that they had seen or heard about something related to pulses in the media or in advertising since January 2016. 28% of Canadian consumers and 36% of US consumers believe that what they saw or read about pulses has led to an increase in pulse consumption."

The Canadian statistics are not quite as readily available, but the following tables show numbers for the supply and disposition of Total Pulse and Special Crops for the years from 2010 to 2013, and then 2015 to 2018. Total domestic use for these crops went from 769,000 metric tonnes in 2010-11 to 1,914,000 metric tonnes in 2016-17, an increase of 250%.

Canada: Principal Field Crops Supply and Disposition

	Area Seeded	Area Harvested	Yield	Production	Imports	Total Supply	Exports	Total Domestic Use	Carry-out Stocks
	— thousand hectares —		t/ha	thousand metric tonnes					
Total Grains And Oilseeds									
2010-2011	23,024	21,618	2.91	62,973	1,867	81,580	32,286	35,906	13,388
2011-2012	23,573	22,667	2.92	66,200	1,342	80,930	34,433	36,065	10,433
2012-2013f	26,289	25,318	2.70	68,458	1,246	80,136	35,085	35,456	9,595
Total Pulse And Special Crops									
2010-2011	3,501	3,318	1.73	5,755	168	7,078	4,788	769	1,521
2011-2012	2,413	2,351	1.93	4,542	121	6,184	3,779	1,217	1,188
2012-2013f	2,763	2,681	1.78	4,778	120	6,086	4,180	941	965
All Principal Field Crops									
2010-2011	26,524	24,936	2.76	68,728	2,035	88,658	37,074	36,675	14,909
2011-2012	25,986	25,017	2.83	70,742	1,463	87,114	38,212	37,282	11,621
2012-2013f	29,052	28,000	2.62	73,237	1,366	86,223	39,265	36,398	10,560

Source: Statistics Canada, f: forecast by Agriculture and Agri-Food Canada

Canada: Principal Field Crops Supply and Disposition

	Area Seeded	Area Harvested	Yield	Production	Imports	Total Supply	Exports	Total Domestic Use	Carry-out Stocks
	- thousand hectares -		*t/ha*	*thousand tonnes*					
Total Grains And Oilseeds									
2015-2016	26,554	25,596	3.08	78,877	2,022	94,452	42,860	39,079	12,514
2016-2017f	25,612	23,791	3.48	82,891	1,963	97,368	41,383	42,230	13,755
2017-2018f	27,256	26,335	3.15	82,840	1,064	97,659	43,343	40,986	13,330
Total Pulse And Special Crops									
2015-2016	3,592	3,556	1.81	6,424	149	7,837	5,554	1,968	315
2016-2017f	4,620	4,475	1.97	8,805	274	9,393	6,599	1,914	880
2017-2018f	3,844	3,778	2.00	7,568	158	8,606	6,111	1,740	755
All Principal Field Crops									
2015-2016	30,146	29,152	2.93	85,302	2,171	102,289	48,414	41,047	12,829
2016-2017f	30,232	28,267	3.24	91,695	2,237	106,761	47,982	44,144	14,635
2017-2018f	31,100	30,113	3.00	90,408	1,222	106,265	49,454	42,726	14,085

Source: Statistics Canada (STC),
f: forecast by AAFC except for area, yield and production for 2016-17 which are STC.

This increase in consumption of pulses and special crops, particularly those subject to desiccation by glyphosate, is evidence and data that is required for an accurate current assessment of glyphosate. However, PRVD2015-01 and PRVD2017-01 both indicated that there were no additional data requirements.
The wording in PVRD2017-01 (at indicated that 8) was:

> ***What Additional Scientific Information is Being Requested?***
> *There are no additional data requirements proposed as a condition of continued registration of glyphosate products.*

The wording in PRVD2015-01 (at 100) was:

> *V.4 Data Gaps*
>
> *"Sufficient information was available to adequately assess the dietary exposure and risk from exposure to glyphosate (all registered, equivalent salt formulations). .... **No deficiencies***

were identified in the residue chemistry database from previous PMRA reviews. No further data are required.

Based on these statements that no further data are required, it would appear that the food consumption data that was used as the basis for the dietary risk assessment is from 1998. At best it is from 2010. Such an assessment is inadequate from an evidentiary perspective, because it ignores 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.

4) MRLs for Unregistered Products Have Not Been Set as Required by the Act

The legislation on the establishment of MRLs for pest control products is the Act. Section 9 deals with setting MRLs for registered products. Section 10 deals with setting MRLs for pest control products that are (a) not registered or that (b) are registered for a use that is not provided for by its registration. With respect to the latter products, Regulatory Directive: Minor Use Requested Minor Use Label Expansion (**"URMULE"**) can apply.

For convenience, sections 9, 10 and 11 of the Act are set out here:

Maximum Residue Limits
Specification at time of registration decision
9 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.

Specification for unregistered products and uses
10 (1) The Minister may specify maximum residue limits for an unregistered pest control product or its components or derivatives, or for a registered pest control product or its components or derivatives with respect to a use that is not provided for by its registration, whether or not an application under subsection (2) is made for that purpose.

Application for specification
(2) Any person may make an application to the Minister to specify maximum residue limits pursuant to subsection (1). Section 7, with any necessary modifications, applies to that application.

Evaluation of health risks
(3) When specifying maximum residue limits for a pest control product or its components or derivatives pursuant to subsection (1), the Minister shall evaluate only the health risks of the product or its components or derivatives.

Health risks to be considered acceptable
11 (1) The health risks associated with maximum residue limits specified by the Minister under sections 9 and 10 must be considered to be acceptable by the Minister.

Subsection 9(3) essentially requires that the Minister evaluate only the health risks of the product in the instances of setting an MRL for a crop that is registered under URMULE.

According to the 2017 Guide to Crop Protection published by the Saskatchewan Ministry of Agriculture (**"2017 Guide"**), chickpeas and other crops are the subject of a URMULE. According to the 2017 Guide (at 235), the use of glyphosate for the use of "Crop Staging for Preharvest Applications" on the crops canary seed, mustard, chickpea, lupin and faba bean is registered under the URMULE program, and because of this "the manufacturer assumes no responsibility for herbicide performance. **Those who apply glyphosate to chickpea, lupin, faba bean, canary seed, camelina or mustard do so at their own risk".**

There is no indication that the use of desiccation/ pre-harvest management on Additional Crops has been looked at or that MRLs have been established for the Additional Crops subject to this use. RVD2017-01 does indicate in Appendix I that MRLs for conventional crops that have been desiccated have been established based on field trial residue studies, but it does not mention the Additional Crops (at 38):

> ***1.3.4 Glyphosate Used as Desiccant and Residue***
> ***Comment***
> *Comments expressed concern about the use of glyphosate for pre-harvest desiccation on conventional crops, the level of residues left on desiccated crops at harvest and the resulting long-term dietary exposure*
>
> ***PMRA Response***
> *Glyphosate is registered for pre-harvest use (desiccation) on a number of* ***conventional crops including wheat, barley, oats, canola, flax, lentils, peas, dry beans, and soybeans.*** *To support this Use, field trial residue studies were required to determine the level of residues resulting from the pre-harvest desiccations conducted according to the requested use pattern. Maximum residue limits (MRLs) for these crops were established on the basis of the submitted studies. Those MRLs were included in the estimation of short term (acute) as well as long term (chronic) dietary exposures. During PMRA's assessment, no dietary risk concerns were identified, as the levels of exposure estimates were well below the reference doses set for dietary risk assessment (the ARfD and ADI).*

Moreover, it appears from the above quotation that the PMRA set the MRLs for the conventional crops based on submitted studies that determined the levels of residues. A determination of the levels of residues that occur in fact and a consequent setting of equivalent MRLs is not an evaluation of health risks. Again, the Act requires that in this instance health risks be evaluated and only the health risks. It would appear that MRLs have not been set for glyphosate applied as a desiccant on Additional Crops, and where they have been set on conventional crops on the basis of field trial studies, it does not appear that the health risks were considered as is required by the Act.

5) **Label Amendments Don't Address the Risk**

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. The amendments speak only to spray buffer zones (PRVD2015-01 Appendix XII; RVD2017-01 Appendix IV). They do not address the moisture content in crops prior to desiccating.

Moreover, there is no certainty that even if labels were amended to address spraying when moisture content is high that the risk would be mitigated. The literature indicates that it is difficult to desiccate the whole crop at low moisture contents, because the plant matures in different stages, and some parts of it may be wet and others dry: "in indeterminate plants, such as pulses, flowers are produced at the bottom and continue to be produced all the way up as the plant grows. This results in mature pods at the bottom of the plant and greener material at the top....[8]

Also moisture content is determined not only by physiological maturity of the plant, but also by the weather, and the weather cannot be controlled or predicted. By way of example, a major concern in Saskatchewan in 2016 were the pea and lentil crops, because they were suffering from excessive moisture.[9] Heavy rains delayed harvest and rendered desiccated crops slow to dry.[10] If a crop is desiccated and then heavy rains occur, the moisture content can be affected (Cessna, 2002; Zhang 2016; Zhang Thesis). Finally, the determination of moisture content by visual indicators is a subjective determination, and so subject to error. (Zhang Thesis at 62). Moreover, even if visual indicators do provide accurate determinations, they are at best guidance and not prescriptions that can enforced.

Section 2(2) of the Act states:

> *(2) For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.*

Given that no labels are proposed that would mitigate the previously discussed risk to human health from desiccation, and given that any such labels would not with reasonable certainty be effective because of the subjective content of any label and the unpredictability of the weather which can affect moisture content, there is no reasonable certainty that no harm to human health or future generations will result from dietary exposure to glyphosate.

6) No Consideration of Whether Labels are Followed

The successful implementation of the 2015 Decision and the 2017 Decision are both premised on the assumption that labels will be followed, but PVRD2015-01 and RVD2017-01 did not

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[8] Brenzil, *Ibid.*

[9] David Giles, "Pea, lentil crops suffering from too much moisture as Sask. Harvest gets under way" August 4, 2016 Global News

[10] Government of Saskatchewan Crop Report For the Period August 30 to September 5, 2016

consider the fact that labels are not in fact followed in Canada; a fact that has been reported by PMRA.

Health Canada's Pest Management Regulatory Agency/ Regulatory Operations and Regions Branch prepares Compliance and Enforcement Reports. The Report for 2015-2016 indicated that most of the instances of non-compliance for that year were of three types, including "use contrary to the label approved by PMRA" (at 5 and 6).

As an example, in 2015-2016 PMRA carried out a "Fruit and Nut Bearing Trees, Bush and Vine Growers Inspection Program" that inspected 172 growers. **Forty-seven per cent** of the growers were not fully compliant, and **"[t]he majority of the violations** involved worker protection violations related to **not following the label directions**, such as not wearing the proper PPE (73 growers), not respecting the re-entry interval (REI) (32 growers) and the preharvest interval (PHI) (21 growers).

The 2015-2016 Report indicated PMRA conducted a monitoring inspection program on 83 pest control operators ("PCOs"), which are specialized users who are specialized commercial users who provide structural and landscaping extermination services. Forty-six per cent of the PCOs were in violation, and "**[t]he most frequent violations included the use of pest control products contrary to label directions (use not included on the label, incorrect use sites and incorrect rates)**, use or possession of unregistered pest control products, and inadequate use of the PPE.

The Surveillance Program in 2015-2016 verified whether there was a return to compliance based on previous non-compliance and likelihood to re-offend. **Thirty-two per cent** had not returned to compliance.

7) Enforcement of Any Imposed Label Requirements on Desiccants Not Likely

DIR2007-02 Compliance Policy (15 June 2007) outlines the Compliance Policy followed by PMRA. With respect to inspections for compliance, it is stated (at 4):

> *Inspections are conducted to assess or verify compliance by registrants, distributors or pesticide users. The types of inspections include the following:*
> - *monitoring inspections*
> - *surveillance inspections; and*
> - *contingency response inspections.*

Monitoring inspections are planned inspections and they monitor compliance with the Act. Surveillance inspections concern whether a previous violator has returned to compliance. Contingency response inspections, or rapid response inspections, are enforcement responses to non-compliance, which can vary depending on a number of factors.

Even if a moisture content label requirements are put in place for the use of desiccants, it is unlikely that the requirements could or would be enforced adequately, at least under the current enforcement regime. The reason is that the only inspection tool currently in place for the PMRA

that would be applicable is "monitoring inspections". Because the seeds on even one plant have different maturity levels depending on their stage of growth, the inspector would need to examine the crop at the exact time the determination is made, and this would be administratively and practically difficult. He or she would also need to ensure that the moisture content is not increased after desiccation because of rain. Moreover, because the determination of moisture content is a subjective judgement, there is no clear line for when moisture content is appropriate. Enforcement without clear lines is administratively and legally difficult.

Section 2(2) of the Act in effect requires establishment of a reasonable certainty that no harm will result from glyphosate exposure taking into account the labels. For such a certainty to be reasonable, it should be likely that the labels will be followed. Given that labels in fact are not followed, and given that enforcement of any moisture content labels would be practically and administratively difficult if not impossible, it is extremely unlikely that labels as to moisture content would be followed, even if they were imposed.

8) **Unlikely that Following Labels Will Bring No Harm, since Statutory Regime Contemplates Exceedances of MRLs Even When Labels are Followed**

The federal statutory regime even contemplates the scenario where the label is followed but MRLs are nevertheless exceeded. This runs contrary to the presumption in the 2015 Decision and the 2017 Decision that labels will be followed and the assumption that if labels are followed there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product.

Specifically, the *Pesticide Residue Compensation Act* provides compensation for any loss suffered by a farmer as a result of the presence of pesticide in or on an agricultural product of that farmer, if (a) an inspection disclosed the presence of a residue that would render a sale contrary to the Food and Drugs Act (i.e. the MRL would be too high); (b) the pesticide is nevertheless registered or deemed registered under the *Pest Control Products Act*: (c) the pesticide was used in accordance with practices approved, recommended, directed or concurred in by the Minister of Health (i.e. in accordance with label directions); and (d) the Minister is satisfied that the presence of the pesticide is not the fault of the farmer, his employees, agents etc. or those of the previous owner.

This has been described by the Ontario Pesticides Education Program at 61 as follows:

> *"This Act pays the producer for damages or losses if the sale of his or her produce is stopped because it contains more pesticide residue than the Food and Drugs Act allows. The producer must prove that the pesticide was applied according to the label directions in order to be considered for compensation. Health Canada administers this Act."*

Thus this compensation act contemplates that MRLs will be exceeded even when label directions are followed. It is difficult for Health Canada to take the position that labels will be followed and therefore no harm will result from glyphosate exposure when the federal statutory regime

contemplates exceedances of MRLs even when labels are followed.

9) Reductions of Safety Factor Without Scientific Rationale

The Act requires the application of a margin of safety, if glyphosate is used in or around homes or schools, that is 10 times great than the margin of safety that would otherwise be applicable, unless the Minister determines "on the basis of reliable scientific data" that a different margin of safety would be appropriate. The relevant provision is Subsection 19(2)(b)(iii):

> *19 (2) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall*
> *(a) ....*
> *(b) in relation to health risks,*
> *(i) ...*
> *(ii) apply appropriate margins of safety to take into account, ...*
> *and*
> *(iii) in the case of a threshold effect, if the product is used in or around homes or schools,* ***apply a margin of safety that is ten times greater*** *than the margin of safety that would otherwise be applicable under subparagraph (ii) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children, unless,* ***on the basis of reliable scientific data,*** *the Minister has determined that a different margin of safety would be appropriate.*

The requirement that the Minister base any decision to lower the safety factor on reliable scientific data is also set out in Re-Evaluation Note REV2010-2 Re-evaluation Work Plan for Glyphosate (2 February 2010). This document summarized the needs for the re-evaluation of glyphosate. With respect to the human health assessment, it was stated (at 2):

- *The assessment will include application of the* ***Pest Control Products Act*** *factors.*
- *Occupational and residential risk assessments will be revised if required should there be any changes to toxicology endpoints or the* ***Pest Control Products Act factors.***
- *Dietary risk is well below the levels of concern based on current modern assessments. New assessments will not be needed provided there are no changes to toxicology endpoints as a result of the* **Pest Control Products Act** ***factor*** *considerations.*

The referenced "Pest Control Products Act factor considerations" are described in Science Policy Note SPN2008-01 The Application of Uncertainty Factors and the *Pest Control Products Act Factor* in the Human Health Risk Assessment of Pesticides (29 July 2008). It is stated:

> *"The PMRA interprets the new PCPA provisions as requiring a presumptive application of the 10-fold factor for the protection of infants and children. In other words, the onus*

> *is on the PMRA to **provide a reliable scientific** rationale in those cases where the 10-fold PCPA factor is reduced....",*

The Conclusion of SPN2008-01 (at 18) is that deviations from the Pest Control Products Act factor require sound scientific justification:

> *"It should be noted that deviations from this guidance would be considered on the basis of developments in science or risk assessment methodologies or changes in policy approach; however, such deviations would require sound scientific justification."*

It appears that PRVD2015-01 reduced the safety factor in at least two instances, without a reliable scientific rationale. The first concerned exposure to children younger than 2 years old. PRVD2015-01 at 28 examines post-application dermal exposure of glyphosate to children 1 to less than 2 years old and incidental oral exposure (hand-to-mouth) from performing postapplication activities in treated lawns/turf + chronic dietary (food and drinking water). This aggregate exposure scenario initially assumed a glyphosate application rate of two applications with a seven day interval. At that application rate, the calculated MOEs for the adult and the youth/children (6 to <11 years old) scenarios reached the target MOE of 100, but the MOE for children (1 to < 2 years old) for the postapplication + incidental oral exposure + chronic dietary scenario did not reach the target of 100. "Therefore... non-dietary refinements were required."

In response to this finding, PMRA simply *changed* the aggregate assessment 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. PMRA stated:

> *[A]ssuming two applications (with a seven-day interval) at the maximum application rate is a highly conservative exposure assumption, as it is **unlikely that children would be exposed to turf residues of the highest rate,** at the lowest interval of application immediately after application. Therefore, a refinement using one application of glyphosate along with a seven-day time-weighted TTR average was used (the average resides of glyphosate were calculated over a seven-day span) for the entire aggregate assessment for all populations.*

The response in RVD2017-01 (at 34, 35) to a comment raising a concern with this "refinement" was to repeat the explanation and add "Using these refinements, all calculated MOEs exceeded the target MOEs and are not of concern to human health".

The refinement in effect decreased the 10-fold factor, by changing the application rates. Had the application rates stayed the same, the 10-fold factor would have been exceeded. There was no scientific justification for this change: just at statement that "it is unlikely that children would be exposed to turf residues of the highest rate, at the lowest interval of application immediately after application". As such, it is contrary to the requirement that there be reliable scientific data for such a change.

The second instance of a reduction in the safety factor concerned the consideration of prenatal or postnatal toxicity. PRVD2015-01 at 17 discussed studies on this point, and stated:

> *"Overall, the endpoints in the young were well characterized.* ***The increased incidence of fetal cardiovascular malformations noted in a rabbit developmental toxicity study was considered a serious endpoint. However, the concern regarding the serious nature of this effect was tempered by the presence of maternal toxicity at the same and lower dose levels in this study.*** *Therefore, the Pest Control Products Act factor was reduced to three-fold when this endpoint was used to establish the point of departure. For all other scenarios, the Pest Control Products Act factor was reduced to one-fold since there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children."*

However, the tempering of the concern surrounding the "serious endpoint" does not appear to be permitted, based on the approach outlined in SPN2008-01. In the description in SPN2008-01 of the consideration of pre-natal or post-natal toxicity it is stated (at 17):

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

Figure 2 at p.21 of SPN2008-01 outlines the approach: First, apply the 10-fold PCPA factor. Then if either a) there are residual uncertainties with respect to completeness of data with respect to the toxicity of infants and children, or b) there are residual concerns relating to prenatal or postnatal toxicity, then the PCPA factor can be modified as required.

It would appear that the increased incidence of fetal cardiovascular malformations in the rabbit developmental toxicity study was a serious endpoint. As such, the 10-fold PCPA factor should have been retained. The fact that there was also maternal toxicity does not detract from the seriousness of the toxicity to the fetuses. There did not appear to be a concern with the completeness of data or residual concerns relating to prenatal or postnatal toxicity, so based on the approach outlined in SPN2008-01, the safety factor should have been retained.

In addition, it is noteworthy that Re-Evaluation Note REV2010-2 Re-evaluation Work Plan for Glyphosate indicates that a new assessment is needed for dietary risk when there are changes to toxicology endpoints (see above). There is no indication that a new assessment was carried out.

Conclusion

It would appear there are threats of serious damage to the health of peoples who consume crops desiccated by glyphosate in Canada. The levels of residues in crops that are desiccated when the moisture content is high have exceeded MRLs in field studies, and recent CFIA data indicates such exceedances are occurring in fact sin Canada. Foods that exceed the established MRL pose a health risk. An evaluation of glyphosate in the use of desiccation did not occur in PRVD2015-

01 or RVD2017-01, and MRLs for the use of desiccation in non-conventional crops do not appear to have been established in accordance with the Act; even though consumption of these crops is increasing markedly. It is submitted that a board of review be struck to assess glyphosate in this context.

Such an evaluation is critical for Canada for two reasons. First, Canadians are likely consuming crops that contain unacceptable levels of glyphosate residue. Second, many of our desiccated legume crops are exported to countries whose MRLs are lower than Canada's. Canada now accounts for approximately 37% of world pulse trade, and is the world's largest producer and exporter. Appropriate regulation of glyphosate applications in these arenas will contribute to enhanced trade.

President, Safe Food Matters Inc.

APPENDIX I
GLYPHOSATE IN CHICKPEAS – CFIA TESTS

APPENDIX II
GLYPHOSATE IN WHEAT BRAN – TONY MITRA - CFIA

Glyphosate in Chickpea - CFIA tests

SR	SAMPLE_NO	Region_Name	Plan_Code	Product Type	ORIGIN_E	DOM_IMP	DateSample	Dt_Recd	Dt_Rept	Commodity	PROGRAM	ANNALYTE	AMMOUNT (ppm)	Report Unit	Program Assessment for FDR 4(d)	Dt-Analyzed	Sample_Type
1	C2015PEST01691	WEST	2015_SB454	Chickpea Products	CANADA	Domestic	2015-07-07	2015-07-09	2015-10-21	IMFD	GLYPHOSATE	Glyphosate	3.16	µg/g	Violation	2015-10-20	FRIED CHICKPEA SNACK
2	C2015PEST01721	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-08-06	2015-08-14	2015-11-01	IMFD	GLYPHOSATE	Glyphosate	2.63	µg/g	Violation	2015-10-29	CHICKPEAS
3	C2015PEST00468	ONTARIO	2015_SB454	Chickpea	CANADA	Domestic	2015-08-24	2015-08-27	2015-11-01	IMFD	GLYPHOSATE	Glyphosate	2.44	µg/g	Violation	2015-10-29	CHICKPEAS
4	C2015PEST00166	ONTARIO	2015-SB454	Chickpea	UNKNOWN	Unknown	2015-05-12	2015-05-19	2015-07-30	IMFD	GLYPHOSATE	Glyphosate	2.41	µg/g	Violation	2015-07-28	Chickpeas
5	C2015PEST01557	WEST	2015_SB454	Chickpea	UNITED STATES	Import	2016-01-02	2016-01-05	2016-04-07	IMFD	GLYPHOSATE	Glyphosate	2.36	µg/g	Violation	2016-04-07	CHICKPEAS
6	C2015PEST00076	ATLANTIC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-09-03	2015-09-16	2015-12-08	IMFD	GLYPHOSATE	Glyphosate	1.42	µg/g	Violation	2015-12-08	Chickpeas (Garbanzo Beans)
7	C2015PEST00578	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-09-15	2015-09-17	2015-12-08	IMFD	GLYPHOSATE	Glyphosate	1.14	µg/g	Violation	2015-12-08	CHICKPEAS
8	C2015PEST01130	QUEBEC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-10-01	2015-10-06	2015-11-26	IMFD	GLYPHOSATE	Glyphosate	1.03	µg/g	Violation	2015-11-18	CHICKPEAS
9	C2015PEST01231	QUEBEC	2015_SB454	Chickpea	UNITED STATES	Import	2015-11-16	2015-11-18	2015-12-17	IMFD	GLYPHOSATE	Glyphosate	0.962	µg/g	Violation	2015-12-17	ORGANIC GARBANZO BEANS
10	C2015PEST01963	WEST	2015_SB454	Chickpea	UNITED STATES	Import	2016-02-12	2016-02-19	2016-04-07	IMFD	GLYPHOSATE	Glyphosate	0.92	µg/g	Violation	2016-04-07	CHICKPEAS
11	C2015PEST01732	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-08-06	2015-08-14	2015-11-01	IMFD	GLYPHOSATE	Glyphosate	0.79	µg/g	Violation	2015-10-29	CHICKPEAS NO SALT ADDED
12	C2015PEST01131	QUEBEC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-10-14	2015-10-16	2015-12-04	IMFD	GLYPHOSATE	Glyphosate	0.28	µg/g	Violation	2015-12-04	Chana - ChickPeas - Pois Chiches
13	C2015PEST01316	QUEBEC	2015_SB454	Chickpea Products	UNITED STATES	Import	2016-01-11	2016-01-14	2016-04-08	IMFD	GLYPHOSATE	Glyphosate	0.264	µg/g	Violation	2016-04-08	HUMMUS - CLASSIC (GLUTEN FREE)
14	C2015PEST01909	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-10	2015-12-15	2016-03-18	IMFD	GLYPHOSATE	Glyphosate	0.219	µg/g	Violation	2016-03-17	SMOKY CHILI & LIME FLAVOURED CHICKPEA SNACK
15	C2015PEST01909	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-10	2015-12-15	2016-03-18	IMFD	GLYPHOSATE	Glyphosate	0.219	µg/g	Violation	2016-03-17	SMOKY CHILI & LIME FLAVOURED CHICKPEA SNACK
16	C2015PEST01822	WEST	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-10-13	2015-10-16	2015-12-08	IMFD	GLYPHOSATE	Glyphosate	0.165	µg/g	Violation	2015-12-08	CHICKPEA CANNED
17	C2015PEST01081	QUEBEC	2015_SB454	Chickpea Products	UNKNOWN	Unknown	2015-09-09	2015-09-11	2015-11-16	IMFD	GLYPHOSATE	Glyphosate	0.157	µg/g	Violation	2015-11-12	CHICKPEA DIP (HUMMUSTAHINA)
18	C2015PEST00979	QUEBEC	2015_SB454	Chickpea Products	LEBANON	Import	2016-01-06	2016-01-08	2016-04-09	IMFD	GLYPHOSATE	Glyphosate	0.149	µg/g	Violation	2016-04-08	CHICKPEA DIP (HUMMUS)
19	C2015PEST01315	QUEBEC	2015_SB454	Chickpea Products	LEBANON	Import	2016-01-21	2016-01-22	2016-03-29	IMFD	GLYPHOSATE	Glyphosate	0.144	µg/g	Violation	2016-03-24	CHICKPEA DIP HUMMUS
20	C2015PEST00146	ATLANTIC	2015-SB454	Chickpea	UNKNOWN	Unknown	2016-02-10	2016-02-10	2016-03-31	IMFD	GLYPHOSATE	Glyphosate	0.105	µg/g	Violation	2016-03-30	Chickpeas
21	C2015PEST01136	QUEBEC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-10-01	2015-10-06	2015-11-26	IMFD	GLYPHOSATE	AMPA	0.077	µg/g	Violation	2015-11-18	CHICKPEAS
22	C2015PEST00166	ONTARIO	2015-SB454	Chickpea	UNKNOWN	Unknown	2015-05-12	2015-05-19	2015-07-30	IMFD	GLYPHOSATE	AMPA	0.0382	µg/g	Violation	2015-07-28	Chickpeas
23	C2015PEST01731	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-08-06	2015-08-14	2015-11-19	IMFD	GLYPHOSATE	AMPA	0.0208	µg/g	Violation	2015-10-29	CHICKPEAS
24	C2015PEST00076	ATLANTIC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-09-03	2015-09-16	2015-12-08	IMFD	GLYPHOSATE	AMPA	0.0173	µg/g	Violation	2015-11-18	Chickpeas (Garbanzo Beans)
25	C2015PEST01081	QUEBEC	2015_SB454	Chickpea Products	UNKNOWN	Unknown	2015-09-09	2015-09-11	2015-11-16	IMFD	GLYPHOSATE	AMPA	0.0103	µg/g	Violation	2015-11-12	CHICKPEA DIP (HUMMUSTAHINA)
26	C2015PEST01732	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-08-06	2015-08-14	2015-11-19	IMFD	GLYPHOSATE	AMPA	0.0094	µg/g	Violation	2015-10-29	CHICKPEAS NO SALT ADDED
27	C2015PEST00407	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-06-01	2015-06-04	2015-10-21	IMFD	GLYPHOSATE	Glyphosate	3.31	µg/g	No Violation	2015-10-20	ORGANIC CHICKPEAS
28	C2015PEST01858	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-06-17	2015-06-23	2015-10-21	IMFD	GLYPHOSATE	Glyphosate	2.61	µg/g	No Violation	2015-10-20	CHICKPEAS CANNED
29	C2015PEST01907	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-07	2015-12-11	2016-04-07	IMFD	GLYPHOSATE	Glyphosate	2.56	µg/g	No Violation	2016-04-06	ORIGINAL SALTED CHICKPEAS
30	C2015PEST01907	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-07	2015-12-11	2016-04-07	IMFD	GLYPHOSATE	Glyphosate	2.58	µg/g	No Violation	2016-04-06	ORIGINAL SALTED CHICKPEAS
31	C2015PEST01908	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-07	2015-12-11	2016-04-07	IMFD	GLYPHOSATE	Glyphosate	1.05	µg/g	No Violation	2016-04-06	SMOKY CHILI & LIME CHICKPEAS
32	C2015PEST01908	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-07	2015-12-11	2016-04-07	IMFD	GLYPHOSATE	Glyphosate	1.05	µg/g	No Violation	2016-04-06	SMOKY CHILI & LIME CHICKPEAS
33	C2015PEST01367	QUEBEC	2015_SB454	Chickpea Products	UNITED STATES	Import	2016-02-06	2016-02-12	2016-04-07	IMFD	GLYPHOSATE	Glyphosate	1.04	µg/g	No Violation	2016-04-07	CRISPY & CRUNCHY CHICKPEAS - ORIGINAL SALTED
34	C2015PEST00467	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-08-18	2015-08-20	2015-11-01	IMFD	GLYPHOSATE	Glyphosate	0.922	µg/g	No Violation	2015-10-29	CHICKPEAS
35	C2015PEST01233	QUEBEC	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-05	2015-12-08	2016-01-08	IMFD	GLYPHOSATE	Glyphosate	0.858	µg/g	No Violation	2016-01-08	CHICKPEAS (ORIGINAL SALTED)
36	C2015PEST01498	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-10-18	2015-10-22	2015-12-08	IMFD	GLYPHOSATE	Glyphosate	0.416	µg/g	No Violation	2015-12-08	ORIGINAL SALTED CHICKPEAS GLUTEN FREE
37	C2015PEST00528	ONTARIO	2015_SB454	Chickpea Products	CANADA	Domestic	2015-08-31	2015-09-03	2015-11-18	IMFD	GLYPHOSATE	Glyphosate	0.16	µg/g	No Violation	2015-11-13	CHICKPEAS FLOUR CHIPS
38	C2015PEST00043	ATLANTIC	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-08-03	2015-08-07	2015-10-29	IMFD	GLYPHOSATE	Glyphosate	0.157	µg/g	No Violation	2015-10-28	Chickpeas Crispy & Crunchy Smoky Chili & Lime Gluten Free
39	C2015PEST00408	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-06-01	2015-06-04	2015-07-15	IMFD	GLYPHOSATE	Glyphosate	0.12	µg/g	No Violation	2015-07-14	CHICKPEAS
40	C2015PEST01080	QUEBEC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-09-08	2015-09-09	2015-11-16	IMFD	GLYPHOSATE	Glyphosate	0.115	pg/g	No Violation	2015-11-13	CHICKPEAS- KABULI CHANA- POIS CHICHES
41	C2015PEST01486	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-10-20	2015-10-22	2015-12-08	IMFD	GLYPHOSATE	Glyphosate	0.0992	µg/g	No Violation	2015-12-08	SWEET CINNAMON CHICKPEAS GLUTEN FREE
42	C2015PEST00529	ONTARIO	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-08-23	2015-08-27	2015-10-28	IMFD	GLYPHOSATE	Glyphosate	0.0938	µg/g	No Violation	2015-10-28	CRISPY & CRUNCHY SWEET CINNAMON CHICKPEAS
43	C2015PEST00577	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-09-15	2015-09-17	2015-11-16	IMFD	GLYPHOSATE	Glyphosate	0.0791	µg/g	No Violation	2015-11-12	CHICKPEAS
44	C2015PEST00013	ATLANTIC	2015-SB454	Chickpea Products	CANADA	Domestic	2015-05-20	2015-05-22	2015-07-15	IMFD	GLYPHOSATE	Glyphosate	0.0783	µg/g	No Violation	2015-07-14	Premium Selection Boondi Chickpea Puffs
45	C2015PEST00407	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-06-01	2015-06-04	2015-10-21	IMFD	GLYPHOSATE	AMPA	0.0622	µg/g	No Violation	2015-10-20	ORGANIC CHICKPEAS
46	C2015PEST00031	ATLANTIC	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-06-20	2015-06-25	2015-08-19	IMFD	GLYPHOSATE	Glyphosate	0.0452	µg/g	No Violation	2015-08-13	Original Salted Chickpeas
47	C2015PEST01652	WEST	2015_SB454	Chickpea Products	UNKNOWN	Unknown	2015-07-19	2015-07-29	2015-08-19	IMFD	GLYPHOSATE	Glyphosate	0.0383	µg/g	No Violation	2015-08-13	FALAFEL SAVOURY CHICKPEA & HERB SNACK
48	C2015PEST01850	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-06-17	2015-06-23	2015-10-21	IMFD	GLYPHOSATE	AMPA	0.0374	µg/g	No Violation	2015-10-20	CHICKPEAS CANNED
49	C2015PEST01435	WEST	2015_SB454	Chickpea Products	UNKNOWN	Unknown	2015-07-05	2015-07-07	2015-08-25	IMFD	GLYPHOSATE	Glyphosate	0.0346	µg/g	No Violation	2015-08-13	MESQUITE BBQ CHICKPEAS GLUTEN FREE
50	C2015PEST00167	ONTARIO	2015-SB454	Chickpea Products	LEBANON	Import	2015-05-21	2015-05-26	2015-07-15	IMFD	GLYPHOSATE	Glyphosate	0.0302	µg/g	No Violation	2015-07-14	Hummus - Chickpea Dip
51	C2015PEST01730	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-08-04	2015-08-07	2015-08-20	IMFD	GLYPHOSATE	Glyphosate	0.0268	µg/g	No Violation	2015-08-18	CHICKPEAS DRIED
52	C2015PEST00164	ONTARIO	2015-SB454	Chickpea Products	UNKNOWN	Unknown	2015-05-13	2015-05-19	2015-06-29	IMFD	GLYPHOSATE	Glyphosate	0.025	µg/g	No Violation	2015-06-28	Crunchy Roasted Chickpeas Barbeque
53	C2015PEST00634	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-10-06	2015-10-0815:0	2015-12-04	IMFD	GLYPHOSATE	Glyphosate	0.0243	µg/g	No Violation	2015-12-04	CHICKPEAS NO SALT ADDED
54	C2015PEST00222	ONTARIO	2015-SB454	Chickpea Products	UNKNOWN	Unknown	2015-09-11	2015-09-16	2015-11-26	IMFD	GLYPHOSATE	Glyphosate	0.0226	µg/g	No Violation	2015-11-18	Roasted Chickpeas - Balsamic & Cracked Pepper
55	C2015PEST00468	ONTARIO	2015_SB454	Chickpea	CANADA	Domestic	2015-08-24	2015-08-27	2015-11-19	IMFD	GLYPHOSATE	AMPA	0.022	µg/g	No Violation	2015-10-29	CHICKPEAS
56	C2015PEST01734	WEST	2015_SB454	Chickpea Products	INDIA	Import	2015-08-04	2015-08-07	2015-08-20	IMFD	GLYPHOSATE	Glyphosate	0.0213	µg/g	No Violation	2015-08-18	BOONDI CHICKPEA BALLS
57	C2015PEST00351	ONTARIO	2015_SB454	Chickpea Products	CANADA	Domestic	2015-05-16	2015-05-20	2015-06-29	IMFD	GLYPHOSATE	Glyphosate	0.02	µg/g	No Violation	2015-06-28	CHANNA FRIED CHICKPEAS SNACK
58	C2015PEST01456	WEST	2015_SB454	Chickpea Products	UNKNOWN	Unknown	2015-08-05	2015-08-10	2015-10-28	IMFD	GLYPHOSATE	Glyphosate	0.0195	µg/g	No Violation	2015-10-28	ROASTED CHICKPEAS BARBEQUE
59	C2015PEST00182	ONTARIO	2015-SB454	Chickpea Products	UNKNOWN	Unknown	2015-06-09	2015-06-15	2015-07-30	IMFD	GLYPHOSATE	Glyphosate	0.0177	µg/g	No Violation	2015-07-27	Roasted Chickpea Barbecue
60	C2015PEST00762	ONTARIO	2015SB454	Chickpea	INDIA	Import	2015-12-11	2015-12-16	2016-04-06	IMFD	GLYPHOSATE	Glyphosate	0.0176	Hg/g	No Violation	2016-01-22	GREEN DESI CHICKPEAS
61	C2015PEST00978	QUEBEC	2015_SB454	Chickpea Products	LEBANON	Import	2015-07-23	2015-07-24	2015-08-25	IMFD	GLYPHOSATE	Glyphosate	0.0171	µg/g	No Violation	2015-08-13	CHICKPEAS DIP
62	C2015PEST00636	QUEBEC	2015_SB454	Chickpea Products	CANADA	Domestic	2015-06-05	2015-06-09	2015-07-30	IMFD	GLYPHOSATE	Glyphosate	0.0169	µg/g	No Violation	2015-07-27	CHANNA- FRIED CHICKPEAS - READYTO EAT SNACK
63	C2015PEST01233	QUEBEC	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-12-05	2015-12-08	2016-01-08	IMFD	GLYPHOSATE	AMPA	0.0169	µg/g	No Violation	2016-01-08	CHICKPEAS (ORIGINAL SALTED)
64	C2015PEST00467	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-08-18	2015-08-20	2015-11-19	IMFD	GLYPHOSATE	AMPA	0.0162	µg/g	No Violation	2015-10-29	CHICKPEAS
65	C2015PEST00147	ATLANTIC	2015-SB454	Chickpea Products	UNKNOWN	Unknown	2015-09-03	2015-09-16	2015-11-26	IMFD	GLYPHOSATE	Glyphosate	0.0147	µg/g	No Violation	2015-11-18	Roasted Chickpea Barbecue Gluten Free
66	C2015PEST01436	WEST	2015_SB454	Chickpea Products	UNKNOWN	Unknown	2015-07-18	2015-07-21	2015-08-25	IMFD	GLYPHOSATE	Glyphosate	0.0142	µg/g	No Violation	2015-08-13	ROASTED CHICKPEAS BALSAMIC & CRACKED PEPPER
67	C2015PEST00578	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-09-15	2015-09-17	2015-12-08	IMFD	GLYPHOSATE	AMPA	0.01	µg/g	No Violation	2015-12-08	CHICKPEAS
68	C2015PEST00098	ONTARIO	2015_SB454	Chickpea	CANADA	Domestic	2015-11-22	2015-11-26	2015-12-22	IMFD	GLYPHOSATE	Glyphosate	0.0079	µg/g	No Violation	2015-12-18	CHICKPEAS (GARBANZO BEANS)
69	C2015PEST01392	WEST	2015_SB454	Chickpea	UNITED STATES	Import	2015-05-20	2015-05-22	2015-06-22	IMFD	GLYPHOSATE	Glyphosate	0.0059	µg/g	No Violation	2015-06-18	CHICKPEAS
70	C2015PEST00977	QUEBEC	2015_SB454	Chickpea	PORTUGAL	Import	2015-08-03	2015-08-05	2015-10-28	IMFD	GLYPHOSATE	Glyphosate	0.0055	µg/g	No Violation	2015-10-28	CHICKPEAS
71	C2015PEST01498	WEST	2015_SB454	Chickpea Products	UNITED STATES	Import	2015-10-18	2015-10-22	2015-12-08	IMFD	GLYPHOSATE	AMPA	0.0051	µg/g	No Violation	2015-12-08	ORIGINAL SALTED CHICKPEAS GLUTEN FREE
72	C2015PEST00181	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-06-09	2015-06-15	2015-07-30	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-07-27	Chickpeas
73	C2015PEST01415	WEST	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-06-15	2015-06-17	2015-08-19	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-08-13	CHICKPEAS ORGANIC
74	C2015PEST01851	WEST	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-06-27	2015-06-30	2015-08-20	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-08-18	ORGANIC CHICKPEAS (GARBANZO BEANS)
75	C2015PEST01434	WEST	2015_SB454	Chickpea	TURKEY	Import	2015-07-02	2015-07-06	2015-08-20	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-08-18	ORGANIC CHICKPEAS
76	C2015PEST01890	WEST	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-07-07	2015-07-09	2015-08-25	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-08-18	CANNED CHICKPEAS
77	C2015PEST01029	QUEBEC	2015_SB454	Chickpea	CANADA	Domestic	2015-07-28	2015-07-31	2015-09-04	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-09-03	CHICKPEAS
78	C2015PEST00525	ONTARIO	2015_SB454	Chickpea	TURKEY	Import	2015-08-11	2015-08-14	2015-10-28	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-10-28	ORGANIC CHICKPEAS
79	C2015PEST00526	ONTARIO	2015_SB454	Chickpea	CANADA	Domestic	2015-08-23	2015-08-27	2015-10-28	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-10-28	ORGANIC CHICKPEAS GLUTEN FREE
80	C2015PEST01497	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-10-06	2015-10-08	2015-12-04	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-12-04	KABULI CHANA (KABULI CHICKPEAS)
81	C2015PEST01821	WEST	2015_SB454	Chickpea	CANADA	Domestic	2015-10-13	2015-10-16	2015-12-08	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-12-08	CHICKPEA CANNED
82	C2015PEST01183	QUEBEC	2015_SB454	Chickpea	UNITED STATES	Import	2015-10-29	2015-11-04	2015-12-08	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-12-08	ORGANIC CHICKPEAS
83	C2015PEST00105	ATLANTIC	2015_SB454	Chickpea	UNITED STATES	Import	2015-11-22	2015-11-27	2015-12-22	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-12-18	ORGANIC USA CHICKPEA/GARBANZO BEANS
84	C2015PEST00105	ATLANTIC	2015_SB454	Chickpea	UNITED STATES	Import	2015-11-22	2015-11-27	2015-12-22	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-12-18	ORGANIC USA CHICKPEA/GARBANZO BEANS
85	C2015PEST01232	QUEBEC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-12-01	2015-12-07	2015-12-22	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-12-18	CHICKPEAS
86	C2015PEST00761	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-12-07	2015-12-10	2016-02-15	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-02-12	PREMIUM QUALITY CHICK PEAS - HALAL
87	C2015PEST01230	QUEBEC	2015_SB454	Chickpea	UNITED STATES	Import	2015-12-08	2015-12-10	2016-02-17	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-02-12	ORGANIC GARBANZO BEANS
88	C2015PEST00268	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-12-10	2015-12-23	2016-03-30	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-30	CHICKPEAS
89	C2015PEST01269	QUEBEC	2015_SB454	Chickpea	UNKNOWN	Unknown	2015-12-10	2015-12-15	2016-03-18	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-17	ORGANIC CHICK PEAS - GLUTEN FREE
90	C2015PEST00629	ONTARIO	2015_SB454	Chickpea	AUSTRALIA	Import	2016-01-09	2016-01-13	2016-04-08	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-04-07	BLACK CHICKPEAS KALA CHANA
91	C2015PEST00630	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2016-01-18	2016-01-20	2016-03-29	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-28	ORGANIC CHICK PEAS
92	C2015PEST01946	WEST	2015_SB454	Chickpea	UNKNOWN	Unknown	2016-01-22	2016-01-29	2016-04-06	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-04-05	CHICKPEAS
93	C2015PEST01950	WEST	2015_SB454	Chickpea	ITALY	Import	2016-01-22	2016-01-29	2016-04-06	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-04-05	CHICKPEAS
94	C2015PEST00291	ONTARIO	2015_SB454	Chickpea	UNKNOWN	Unknown	2016-01-28	2016-02-11	2016-03-28	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-24	PREMIUM CHICK PEAS
95	C2015PEST00884	ONTARIO	2015_SB454	Chickpea	TURKEY	Import	2016-02-01	2016-02-04	2016-04-05	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-31	ORGANIC CHICK PEAS
96	C2015PEST00145	ATLANTIC	2015_SB454	Chickpea	UNKNOWN	Unknown	2016-02-03	2016-02-11	2016-03-31	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-30	CHICKPEAS
97	C2015PEST01364	QUEBEC	2015_SB454	Chickpea	TURKEY	Import	2016-02-08	2016-02-12	2016-04-05	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-31	ORG CHICKPEAS
98	C2015PEST00350	ONTARIO	2015-SB454	Chickpea Products	INDIA	Import	2015-05-16	2015-05-20	2015-06-29	IMFD	GLYPHOSATE	Glyphosate screen	Negative	Pos/Neg	Not Assessed	2015-06-28	Masala Chana - Crispy, Spicy, Chickpeas Snack
99	C2015PEST01613	WEST	2015_SB454	Chickpea Products	CANADA	Domestic	2015-06-16	2015-06-23	2015-08-20	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-08-18	CHICKPEA SNACK MEDIUM HOT
100	C2015PEST01733	WEST	2015_SB454	Chickpea Products	INDIA	Import	2015-08-04	2015-08-07	2015-08-20	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-08-18	MASALA CHANA SPICY CHICKPEAS
101	C2015PEST00527	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2015-08-11	2015-08-14	2015-10-29	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-10-28	ROASTED GRAM SPLIT (CHICKPEA FENDRE)
102	C2015PEST00579	ONTARIO	2015_SB454	Chickpea Products	UNKNOWN	Unknown	2015-09-14	2015-09-18	2015-11-16	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-11-13	ROASTED CHICKPEAS
103	C2015PEST01775	WEST	2015_SB454	Chickpea Products	CANADA	Domestic	2015-09-18	2015-09-24	2015-11-16	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-11-12	TIKHA GATHIYA SPICY CHICKPEA FLOUR STICKS
104	C2015PEST00080	ONTARIO	2015_SB454	Chickpea Products	CANADA	Domestic	2015-09-30	2015-10-02	2015-11-16	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-11-12	HOT CHICKPEAS
105	C2015PEST01132	QUEBEC	2015_SB454	Chickpea Products	INDIA	Import	2015-10-01	2015-10-06	2015-11-16	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-11-12	Khatta Meetha - Indian Snacks - Sour & Sweet Mix
106	C2015PEST00635	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2015-10-06	2015-10-08	2015-11-26	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-11-18	CHANA CHOR SPICY PRESSED CHICKPEA
107	C2015PEST00700	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2015-11-09	2015-11-12	2015-12-11	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2015-12-10	ROASTED SALTED CHICKPEAS
108	C2015PEST00763	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2015-12-07	2015-12-10	2016-02-15	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-02-12	CHANA CHOR - SPICY PRESSED CHICKPEA READY TO EAT SNACK
109	C2015PEST00764	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2015-12-07	2015-12-10	2016-02-15	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-02-12	ROASTED CHANA (TUMERIC) (ROASTED CHICKPEAS)
110	C2015PEST00269	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2015-12-10	2015-12-23	2016-03-30	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-30	BOONDI CHICK PEA BALLS
111	C2015PEST00766	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2015-12-11	2015-12-16	2016-01-29	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-01-22	BOONDI CHICK PEAS BALLS
112	C2015PEST00631	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2016-01-09	2016-01-13	2016-04-06	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-04-05	ROASTED SALTED CHICKPEAS
113	C2015PEST01314	QUEBEC	2015_SB454	Chickpea Products	LEBANON	Import	2016-01-21	2016-01-22	2016-03-28	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-24	HOMMOS WITH SESAME PASTE
114	C2015PEST01365	QUEBEC	2015_SB454	Chickpea Products	UNITED STATES	Import	2016-02-03	2016-02-09	2016-03-28	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-24	CHICKPEAS - ORIGINAL SALTED - CRISPY & CRUNCHY
115	C2015PEST01366	QUEBEC	2015_SB454	Chickpea Products	LEBANON	Import	2016-02-06	2016-02-12	2016-03-31	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-30	CHICK PEAS DIP - HUMMUS TAHINA
116	C2015PEST00885	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2016-02-18	2016-02-24	2016-03-18	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-17	CHANA WITH SKIN ROASTED CHICKPEAS
117	C2015PEST00886	ONTARIO	2015_SB454	Chickpea Products	INDIA	Import	2016-02-18	2016-02-24	2016-03-31	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-03-30	CHANA HALDI (SALT) - SALTED ROASTED CHICKPEAS

Glyphosate in wheat bran - CFIA - Tony Mitra

SR	SAMPLE_NO	Region_Name	Plan_Code	Product Type	ORIGIN_E	DOM_IMP	DateSample	Dt_Recd	Dt_Rept	Commodity	PROGRAM	ANNALYTE	AMMOUNT (ppm)	Report Unit	Program Assessment for FDR 4(d)	Dt Analyzed	Sample_Type
1	C2016PEST00349	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-06-10	2016-06-15	2016-10-21	IMFD	GLYPHOSATE	Glyphosate	6.63	µg/g	Violation	2016-10-20	WHEAT BRAN
2	C2016PEST00037	ATLANTIC	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-07-02	2016-07-12	2016-09-29	IMFD	GLYPHOSATE	Glyphosate	4.68	µg/g	No Violation	2016-09-21	WHEAT BRAN
3	C2016PEST00347	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-05-29	2016-05-31	2016-07-30	IMFD	GLYPHOSATE	Glyphosate	4.61	µg/g	No Violation	2016-07-29	WHEAT BRAN
4	C2016PEST00408	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-06-11	2016-06-17	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	4.58	µg/g	No Violation	2016-08-15	WHEAT BRAN
5	C2016PEST01442	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-07-02	2016-07-05	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	4.09	µg/g	No Violation	2016-08-26	WHEAT BRAN
6	C2016PEST00465	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-07-02	2016-07-06	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	4.07	µg/g	No Violation	2016-08-26	WHEAT BRAN
7	C2016PEST00346	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-05-29	2016-05-31	2016-07-30	IMFD	GLYPHOSATE	Glyphosate	4.04	µg/g	No Violation	2016-07-29	WHEAT BRAN
8	C2016PEST00520	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-08-06	2016-08-10	2016-10-21	IMFD	GLYPHOSATE	Glyphosate	3.94	µg/g	No Violation	2016-10-20	WHEAT BRAN
9	C2016PEST00407	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-06-11	2016-06-17	2016-10-21	IMFD	GLYPHOSATE	Glyphosate	3.93	µg/g	No Violation	2016-10-20	ALL NATURAL NO ADDITIVES NO PRESERVATIVES WHEAT BRAN
10	C2016PEST00905	QUEBEC	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-04-11	2016-04-15	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	3.71	µg/g	No Violation	2016-08-15	WHEAT BRAN
11	C2016PEST00290	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-04-03	2016-04-06	2016-04-22	IMFD	GLYPHOSATE	Glyphosate	3.46	µg/g	No Violation	2016-04-20	ALL NATURAL WHEAT BRAN
12	C2016PEST01670	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-06-27	2016-06-29	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	3.4	µg/g	No Violation	2016-08-26	WHEAT BRAN
13	C2016PEST01417	WEST	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-06-05	2016-06-09	2016-07-30	IMFD	GLYPHOSATE	Glyphosate	2.55	µg/g	No Violation	2016-07-28	WHEAT BRAN
14	C2016PEST01441	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-07-02	2016-07-05	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	2.29	µg/g	No Violation	2016-08-26	WHEAT BRAN
15	C2016PEST01638	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-05-11	2016-05-12	2016-07-23	IMFD	GLYPHOSATE	Glyphosate	2.02	µg/g	No Violation	2016-07-05	WHEAT BRAN
16	C2016PEST00345	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-04-29	2016-05-04	2016-07-23	IMFD	GLYPHOSATE	Glyphosate	1.98	µg/g	No Violation	2016-07-05	WHEAT BRAN
17	C2016PEST00466	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-07-04	2016-07-08	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	1.47	µg/g	No Violation	2016-08-25	WHEAT BRAN
18	C2016PEST01596	WEST	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-04-09	2016-04-15	2016-07-23	IMFD	GLYPHOSATE	Glyphosate	1.42	µg/g	No Violation	2016-07-05	WHEAT BRAN 100% NATURAL
19	C2016PEST01069	QUEBEC	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-08-02	2016-08-08	2016-10-17	IMFD	GLYPHOSATE	Glyphosate	1.04	µg/g	No Violation	2016-10-13	WHEAT BRAN - 100% NATURAL WHEAT BRAN
20	C2016PEST01636	WEST	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-05-07	2016-05-13	2016-07-23	IMFD	GLYPHOSATE	Glyphosate	0.686	µg/g	No Violation	2016-07-04	100% NATURAL WHEAT BRAN
21	C2016PEST00145	ONTARIO	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-04-06	2016-04-20	2016-05-31	IMFD	GLYPHOSATE	Glyphosate	0.192	µg/g	No Violation	2016-05-29	Wheat Bran Rich In Dietary Fibre Unprocessed Miller's
22	C2016PEST00520	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-08-06	2016-08-10	2016-10-21	IMFD	GLYPHOSATE	AMPA	0.188	µg/g	No Violation	2016-09-30	WHEAT BRAN
23	C2016PEST00349	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-06-10	2016-06-15	2016-10-21	IMFD	GLYPHOSATE	AMPA	0.159	µg/g	Violation	2016-08-17	WHEAT BRAN
24	C2016PEST00348	ONTARIO	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-05-29	2016-05-26	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	0.0843	pg/g	No Violation	2016-08-10	UNPROCESSED MILLER'S WHEAT BRAN
25	C2016PEST01379	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-04-03	2016-04-06	2016-04-22	IMFD	GLYPHOSATE	Glyphosate	0.068	µg/g	No Violation	2016-04-20	WHEAT BRAN
26	C2016PEST01637	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-05-21	2016-05-26	2016-08-30	IMFD	GLYPHOSATE	Glyphosate	0.066	µg/g	No Violation	2016-08-10	WHEAT BRAN
27	C2016PEST01378	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-04-11	2016-04-14	2016-05-31	IMFD	GLYPHOSATE	Glyphosate	0.0631	µg/g	No Violation	2016-05-27	WHEAT BRAN
28	C2016PEST00947	QUEBEC	2016_SB454	Bran - Wheat	UNKNOWN	Import	2016-05-02	2016-05-05	2016-05-31	IMFD	GLYPHOSATE	Glyphosate	0.0623	µg/g	No Violation	2016-05-29	WHEAT BRAN (ORGANIC)
29	C2016PEST01597	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-04-17	2016-04-22	2016-05-31	IMFD	GLYPHOSATE	Glyphosate	0.0601	µg/g	No Violation	2016-05-29	WHEAT BRAN
30	C2016PEST00982	QUEBEC	2016_SB454	Bran - Wheat	UNKNOWN	Import	2016-06-06	2016-06-10	2016-07-23	IMFD	GLYPHOSATE	Glyphosate	0.0562	µg/g	No Violation	2016-07-11	ORGANIC WHEAT BRAN
31	C2016PEST00407	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-06-11	2016-06-17	2016-10-21	IMFD	GLYPHOSATE	AMPA	0.054	µg/g	No Violation	2016-08-17	ALL NATURAL NO ADDITIVES NO PRESERVATIVES WHEAT BRAN
32	C2016PEST00466	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-07-04	2016-07-08	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.054	µg/g	No Violation	2016-08-17	WHEAT BRAN
33	C2016PEST00290	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-04-03	2016-04-06	2016-04-22	IMFD	GLYPHOSATE	AMPA	0.052	µg/g	No Violation	2016-04-20	ALL NATURAL WHEAT BRAN
34	C2016PEST01596	WEST	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-04-09	2016-04-15	2016-07-23	IMFD	GLYPHOSATE	AMPA	0.0514	µg/g	No Violation	2016-05-29	WHEAT BRAN 100% NATURAL
35	C2016PEST01460	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-08-01	2016-08-03	2016-09-29	IMFD	GLYPHOSATE	Glyphosate	0.0467	µg/g	No Violation	2016-09-08	WHEAT BRAN
36	C2016PEST01671	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-06-04	2016-06-10	2016-07-30	IMFD	GLYPHOSATE	Glyphosate	0.0464	µg/g	No Violation	2016-07-29	WHEAT BRAN
37	C2016PEST00465	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-07-02	2016-07-06	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0441	µg/g	No Violation	2016-08-10	WHEAT BRAN
38	C2016PEST01442	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-07-02	2016-07-05	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0408	µg/g	No Violation	2016-08-10	WHEAT BRAN
39	C2016PEST01397	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-05-01	2016-05-03	2016-05-312 :24	IMFD	GLYPHOSATE	AMPA	0.0407	µg/g	No Violation	2016-05-31	WHEAT BRAN
40	C2016PEST01417	WEST	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-06-05	2016-06-09	2016-07-30	IMFD	GLYPHOSATE	AMPA	0.0367	µg/g	No Violation	2016-07-11	WHEAT BRAN
41	C2016PEST01670	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-06-27	2016-06-29	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0367	µg/g	No Violation	2016-08-10	WHEAT BRAN
42	C2016PEST01441	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-07-02	2016-07-05	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0337	µg/g	No Violation	2016-08-10	WHEAT BRAN
43	C2016PEST00905	QUEBEC	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-04-11	2016-04-15	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0298	µg/g	No Violation	2016-07-29	WHEAT BRAN
44	C2016PEST00345	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-04-29	2016-05-04	2016-07-23	IMFD	GLYPHOSATE	AMPA	0.0277	µg/g	No Violation	2016-05-22	WHEAT BRAN
45	C2016PEST00408	ONTARIO	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-06-11	2016-06-17	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0251	µg/g	No Violation	2016-07-29	WHEAT BRAN
46	C2016PEST00346	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-05-29	2016-05-31	2016-07-30	IMFD	GLYPHOSATE	AMPA	0.025	µg/g	No Violation	2016-07-29	WHEAT BRAN
47	C2016PEST00347	ONTARIO	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-05-29	2016-05-31	2016-07-30	IMFD	GLYPHOSATE	AMPA	0.0243	µg/g	No Violation	2016-07-29	WHEAT BRAN
48	C2016PEST01636	WEST	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-05-07	2016-05-13	2016-07-23	IMFD	GLYPHOSATE	AMPA	0.0149	µg/g	No Violation	2016-05-20	100% NATURAL WHEAT BRAN
49	C2016PEST01638	WEST	2016_SB454	Bran - Wheat	UNKNOWN	Unknown	2016-05-11	2016-05-12	2016-07-23	IMFD	GLYPHOSATE	AMPA	0.0139	µg/g	No Violation	2016-05-29	WHEAT BRAN
50	C2016PEST00348	ONTARIO	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-05-25	2016-05-26	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0104	µg/g	No Violation	2016-08-10	UNPROCESSED MILLER'S WHEAT BRAN
51	C2016PEST01460	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-08-01	2016-08-03	2016-09-29	IMFD	GLYPHOSATE	AMPA	0.0104	µg/g	No Violation	2016-09-08	WHEAT BRAN
52	C2016PEST01597	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-04-17	2016-04-22	2016-05-31	IMFD	GLYPHOSATE	AMPA	0.009	µg/g	No Violation	2016-05-29	WHEAT BRAN
53	C2016PEST01379	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-04-03	2016-04-06	2016-04-22	IMFD	GLYPHOSATE	AMPA	0.008	µg/g	No Violation	2016-04-20	WHEAT BRAN
54	C2016PEST01637	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-05-21	2016-05-26	2016-08-30	IMFD	GLYPHOSATE	AMPA	0.0078	µg/g	No Violation	2016-08-10	WHEAT BRAN
55	C2016PEST01671	WEST	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-06-04	2016-06-10	2016-07-30	IMFD	GLYPHOSATE	AMPA	0.007	µg/g	No Violation	2016-07-29	WHEAT BRAN
56	C2016PEST00001	ATLANTIC	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-04-12	2016-04-14	2016-05-31	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-05-27	WHEAT BRAN
57	C2016PEST00983	QUEBEC	2016_SB454	Bran - Wheat	CANADA	Domestic	2016-05-13	2016-05-17	2016-07-30	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-07-29	ORGANIC WHEAT BRAN
58	C2016PEST00050	ATLANTIC	2016_SB454	Bran - Wheat	UNITED STATES	Import	2016-08-03	2016-08-05	2016-09-29	IMFD	GLYPHOSATE	Glyphosate Screen	Negative	Pos/Neg	Not Assessed	2016-09-26	WHEAT BRAN

Health Canada | Santé Canada

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

Reference No. 2017-3047

September 29, 2022

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

Dear Ms. McDonald,

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

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

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

Legislative and Regulatory Framework for Decision

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

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

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

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

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

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

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

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

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

Section 3 of the *Regulations* states:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Summary of the Notice of Objection under Review

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

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

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

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

PMRA's Consideration of the Objections:

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

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

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

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

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

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

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

Pre-harvest use versus Desiccant use:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MRL exceedances do not equate to a health risk:

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

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

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

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[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[1] 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Health Canada's conclusions on the regulatory acceptability of glyphosate regarding the dietary risk from the consumption of crops that may be treated with glyphosate are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally[p][q]. 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

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[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?'**

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[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

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[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

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[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

Reference list

References cited in the Safe Food Matters Inc. Notice of Objection:

Benzil, C. 2012, provincial weed specialist with the Saskatchewan Ministry of Agriculture, as quoted in Angela Lovell, "Don't use desiccants to hasten maturity", Grainews (4 June 2012), online: <www.grainews.ca>

Bond, J. 2017. "Pulses Production Expanding as Consumers Cultivate a Taste for U.S. Lentils and Chickpeas." Amber Waves: The Economics of Food, Farming, Natural Resources, and Rural America. United States Department of Agriculture. Last accessed online May 26, 2022 at https://www.ers.usda.gov/amber-waves/2017/januaryfebruary/pulses-production-expanding-as-consumers-cultivate-a-taste-for-us-lentils-and-chickpeas/

Calles, T., del Castello, R., Baratelli, M., Xipsiti, M. and Navarro, D.K. 2019. 2016 The International Year of Pulses - Final report. Rome. FAO. 40 pp.

Cessna, A. J. Darwent, A. L. Townley-Smith, L. Harker, K. N. Kirkland, K. 2002. Residues of glyphosate and its metabolite AMPA in field pea, barley and flax seed following preharvest applications. Canadian Journal of Plant Science, 82(2): 485-489.

Cessna, A.J. Darwent, A. L. Townley-Smith, L. Harker, K.N. Kirkland, K.J. 2000. Residues of glyphosate and its metabolite AMPA in canola seed following preharvest applications. Canadian Journal of Plant Science, 80(2): 425-431.

Cessna, A.J. Darwent, A.L. Kirkland, K.J. Townley-Smith, L. Harker, K.N. Lefkovitch, L.P. 1994. Residues of glyphosate and its metabolite AMPA in wheatseed and foliage following preharvest applications. Canadian Journal of Plant Science, 74(3): 653-661.

Gabison Y 2014. The Dip That Roared: How Humus Conquered the US. June 20, 2014 Haaretz.com

Gaultier, J. Gulden, R. 2016. The science and art of dry bean desiccation. Crops and Soils, 49(4): 12-15.

Giles, D 2016. "Pea, lentil crops suffering from too much moisture as Sask. Harvest gets under way" August 4, 2016 Global News

Health Canada's Pest Management Regulatory Agency / Regulatory Operations and Regions Branch Compliance and Enforcement Report 2015-2016. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt_formats/pdf/pubs/pest/corp-plan/compliance-enforcement-2015-2016-conformite-application/compliance-enforcement-2015-2016-conformite-application-eng.pdf

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.

McNaughton, K.E. Blackshaw, R.E. Waddell, K.A. Gulden, R.H. Sikkema, P.H. Gillard, C.L. 2015. Effect of Application Timing of Glyphosate and saflufenacil as desiccants in dry edible bean (*Phaseolus vulgaris* L). Canadian Journal of Plant Science, 95(2): 369-375.

Mitra, T. 2017. "Glyphosate in chickpea, lentil and wheat bran." Last accessed online May 26, 2022 at http://www.tonu.org/2017/06/15/glyphosate-in-chickpea-lentil-and-wheat-bran/

Proposed Re-evaluation Decision PRVD2015-01, Glyphosate (13 April, 2015).https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-re-evaluation-decisions/2015/glyphosate/document.html

Re-evaluation Decision RVD2017-01, Glyphosate (28 April 2017). https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2017/glyphosate-rvd-2017-01.html

Saskatchewan Ministry of Agriculture, 2016. Crop Report for the Period August 30 to September 5, 2016.

Saskatchewan Ministry of Agriculture, 2017. Guide to Crop Protection for the Chemical Management of weeds, Plant Diseases, and Insects.

Science Policy Note SPN2003-03, Assessing Exposure from Pesticides, A User's Guide 28 July 2003). https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2003/assessing-exposure-pesticides-food-user-guide-spn2003-03.html

Science Policy Note, SPN2008-01. The Application of Uncertainty Factors and the *Pest Control Products Act Factor* in the Human Health Risk Assessment of Pesticides (29 July 2008).https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2008/application-uncertainty-factors-pest-control-products-act-factor-human-health-risk-assessment-pesticides-spn2008-01.html

Science Policy Note, SPN2014-01, General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments. Last accessed online July 4, 2022 at https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2014/general-exposure-factor-inputs-dietary-occupational-residential-exposure-assessments-spn2014-01.html.

Statistics Canada: Historical Supply and Disposition of Crop Years: 2010-2011 to 2015-2016 – Pulses and Special Crops. https://agriculture.canada.ca/en/market-information-system/rp/index-eng.cfm?action=pR&r=244&pdctc

Zhang, T. Johnson, E.N. Mueller, T.C. Willenborg, C.J. 2017. Early Application of Harvest Aid Herbicides Adversely Impacts Lentil. Agronomy Journal, 109(1): 239-248.

Zhang, T. Johnson, E.N. Willenborg C.J. 2016. Evaluation of Harvest Aids Application Timing for Lentil Dry Down. Weed Technology, 30: 629-638.

Zhang, T. 2015. Evaluation of Herbicides as Desiccants for Lentil (*Lens culinaris* Medik) Production. MSc thesis, University of Saskatchewan, Saskatoon.

Additional References cited in PMRA's Response to the NoO

Canadian Food Inspection Agency. 2017. Safeguarding with Science: Glyphosate Testing in 2015-2016. Last accessed online May 26, 2022 at https://inspection.canada.ca/food-safety-for-industry/food-chemistry-and-microbiology/food-safety-testing-bulletin-and-reports/executive-summary/glyphosate-testing/eng/1491846907641/1491846907985

Codex Classification of Foods and Animal Feeds | Agrisemantics Map of Data Standards www.fao.org/input/download/standards/41/CXA_004_1993e.pdf

Crop Grouping – IR-4 Project https://www.ir4project.org/fc/crop-grouping/

Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks, 1 August, 2000. https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html

Health Canada Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments, 28 August 2019. https://www.canada.ca/content/dam/hc-sc/documents/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/determining-study-acceptability-pesticide-risk-assessments/infonote-determining-study-acceptability-eng.pdf.

Kolakowski, B.M. Miller, L. Murray, A. Leclair, A., Bietlot, H. and van de Riet, J.M. 2020. Analysis of Glyphosate Residues in Food from the Canadian Retail Markets between 2015 and 2017. Journal of Agricultural and Food Chemistry, 68(18): 5201-5211.

PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products 28 July 2021. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/risk-management-pest-control-products.html

Proposed Maximum Residue Limit PMRL2021-10, Glyphosate. https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-maximum-residue-limit/2021/glyphosate/document.html

Regulatory Directive: Residue Chemistry Guidelines (DIR98-02). https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/1998/residue-chemistry-guidelines-dir98-02.html.

Science Policy Note SPN2003-04: General Principles for Performing Aggregate Exposure and Risk Assessments. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-

publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2003/general-principles-performing-aggregate-exposure-risk-assessments-science-spn2003-04.html.

This is **Exhibit "C"** referred to in the Affidavit of Mary Lou McDonald affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely, this 21st day of April, 2023

Bronwyn Roe

Commissioner for Taking Affidavits
Bronwyn Roe, LSO #63840R

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

JAN 11 2019

Reference No. 2017-3047

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

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 reviewed and assessed in accordance with the PCPA and *Review Panel Regulations*.

The purpose of a notice of objection is to identify the area of science supporting the re-evaluation decision to which objection is taken, to provide the scientific basis of the objection and to request that the area of science in question be referred to a review panel for reconsideration and recommendation.

The PMRA has taken all reasonable measures to ensure impartiality in determining if a panel should be established. The notice of objection, including the scientific rationale, was assessed by a team of PMRA evaluators who were not involved in the original re-evaluation decision. This team provided recommendations as to the requirement for a review panel based on the validity and the scientific plausibility of the issues raised in the notice. The factors to be considered in determining whether to establish a review panel include:

- whether the information in the notice 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 pesticide; and
- whether the advice of a review panel of expert scientists would assist in addressing the subject matter of the objection.

The following information was received and reviewed in support of your notice of objection:

- Notice of Objection Form
- Notice of Objection document
- Glyphosate in Chickpea - CFIA tests

- Glyphosate in Wheat Bran - CFIA

The information which you submitted in support of your objection does not meet either of those factors and, accordingly, does not provide a basis for the establishing of a review panel. As a consequence, a review panel will not be established to reconsider the regulatory decision in response to your request.

The issues raised in the notice of objection are attached to this letter are **in bold text,** followed by PMRA responses which are not (see Attachment 1).

Should you have any questions regarding this letter, please contact Charles Smith at 613-736-3625 or charles.smith@canada.ca. Please quote Reference Number 2017-3048 in any correspondence regarding the Notice of Objection to re-evaluation of glyphosate.

Yours truly,

Peter Brander
Chief Registrar
Pest Management Regulatory Agency

Attachment 1

Comment 1: A comment was received which objected to reductions of the safety factor without scientific rationale with regards to the serious endpoint of cardiovascular malformations in the rabbit developmental toxicity study. The objector indicates that the tempering of the concern surrounding the "serious endpoint" based on the presence of maternal toxicity does not appear to be permitted, based on the approach outlined in SPN2008-01.

PMRA Response:

While SPN2008-01[a] does not explicitly state that there is a reduced level of concern when malformations occur in the presence of maternal toxicity, this scenario does fall within the purview of the first paragraph of Section 4.1 of SPN2008-01:

> Under the new *Pest Control Products Act* (PCPA), the PMRA must apply a default 10-fold factor (the PCPA factor) unless the PMRA concludes, based on reliable data, that a different factor is appropriate for the protection of infants and children. Determination of the magnitude of the factor involves 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). 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. [b]

In determining whether the PMRA can reduce the PCPA factor, the PMRA takes into account contextual information such as the impact of a chemical on the health of the maternal animal. Concern is lessened when fetal toxicity occurs in the presence of maternal toxicity since maternal toxicity, in and of itself, can result in effects on the fetus. Decreased maternal body weight or body weight gain at sensitive stages of development can result in changes in the fetus independent of direct chemical insults on the fetus. For some effects, protecting maternal health will serve to limit fetal exposure and toxicity. For this reason, a higher level of concern reflected

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[a] 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 August, 2018]

[b] Ibid.

in a PCPA factor of 10-fold, is accorded to serious effects that are seen in the fetus but not in the maternal animal.

This is reflected in page 17 of PRVD2015-01, which states "Overall, the endpoints in the young were well characterized. The increased incidence of fetal cardiovascular malformations noted in a rabbit developmental toxicity study was considered a serious endpoint. However, the concern regarding the serious nature of this effect was tempered by the presence of maternal toxicity at the same and lower dose levels in this study. Therefore, the *Pest Control Products Act* factor was reduced to three-fold when this endpoint was used to establish the point of departure. For all other scenarios, the *Pest Control Products Act* factor was reduced to one-fold since there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children."

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

PMRA Response:

The PMRA assessed the scientific literature cited in support of this comment. The cited references show that residues of glyphosate increase when applied as a preharvest treatment when the moisture content in the crop is more than 30%. However, the labels of registered glyphosate products in Canada indicate that application must be conducted at less than 30% moisture content, and the residue data used to establish MRLs were based on this use pattern. In other words, as indicated in the response to comments provided in the final re-evaluation decision document for glyphosate (RVD2017-010), glyphosate residues on foods have been measured in field trial studies that are required to register a pesticide for specific uses, as per PMRA Residue Chemistry Guidelines (Dir98-02). These field trial data were used for the establishment of maximum residue limits (MRLs) for glyphosate, that is, the maximum legally allowed amount of glyphosate residue that may remain on foods when glyphosate is used according to label directions.

With respect to the actual MRLs, they are enforced by law under the *Food and Drugs Act*. The conditions of registration must be observed in all circumstances. It is an offence under the PCPA if the product is not used in accordance with the conditions of registration, including the use directions on the label. MRLs are set at a level well below the amount of residue that could present a human health concern. However, an exceedance of an MRL does not automatically equate to a potential health risk of concern. Nevertheless, when pesticide residue levels exceed the MRL, follow-up actions for non-compliant products, taken by the Canadian Food Inspection

Agency (CFIA), are initiated in a manner that reflects the magnitude of the health concern. Actions may include further analysis, notification of the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

In the case of the glyphosate monitoring undertaken by the CFIA, as indicated in their report, the non-compliant data were evaluated and no human health concerns were identified. The CFIA will continue to monitor for the presence of this commonly used herbicide to help ensure the safety of the Canadian food supply.

Comment 3: A comment was received which stated that it would appear that an examination of the risks arising from dietary exposure to crops that have been desiccated with glyphosate was not part of the re-evaluation, and maintained that such an examination is necessary, particularly given that mechanisms by which MRLs can be exceeded in desiccated crops, and that data from the CFIA indicates that exceedances are occurring.

PMRA Response:

PRVD2015-01, Appendix V, page 99, under "Supervised residues trial studies" 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 preharvest applications** for forage crops (PHI 3-7 days) and all other crops (PHI of 7-14 days)." To further clarify, preharvest applications are the desiccant uses. Thus, the dietary risk assessment conducted in the re-evaluation encompasses all registered food uses, including desiccated crops.

Comment 4: A comment was received which expressed concern regarding PMRA's use of CSFII – 1994-1996, 1998 Continuing Survey of Food Intakes by Individuals, and United States WWEIA consumption data to assess dietary risk in the re-evaluation of glyphosate. Safe Food Matters Inc. argued that a dietary risk assessment using these data is inadequate because of the evidence that current levels of consumption and production of desiccated legumes like chickpeas and lentils has increased dramatically. Accurate information showing the increase in consumption would increase the numbers for the calculations of glyphosate exposure through diet.

PMRA Response:

The PMRA's dietary exposure assessments (for new active ingredients and re-evaluations, such as for glyphosate) rely upon the "Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™ Version 2.14) program, which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998". Prior to using the CSFII, the PMRA compared the exposures from the consumption data from CSFII and the National Health and Nutritional Examination Survey, What We Eat in America (NHANES/ WWEIA). There was consistency in the food intake pattern and no significant differences in exposure were observed. In turn, even with more recent versions of DEEM with

updated consumption data, dietary exposure is not expected to be of concern. It should be noted that dietary estimates are also well below the acceptable daily intake (ADI), as well as the acute reference dose (ARfD): 20 – 70% of the ADI for all segments of the population, 31% of the ARfD for females 13 – 49 years of age, and 12 – 45% of the ARfD for other population subgroups.

It is also important to note that the residue input in DEEM is not directly related to the use scenario of the pesticide. However, if a pesticide is registered for several different use scenarios (e.g. pre-emergent use, early post-emergent use and desiccant use), then the residue level input in DEEM (a single value in ppm) would be the highest residue observed among all the scenarios tested. Therefore, if the use of a desiccant results in the highest residue level, it will be assumed that all legume crops that are consumed contain residues from that desiccant use. In addition, the dietary risk assessment conducted for the glyphosate re-evaluation assumed 100% of registered crops to be treated, which is also a conservative assumption.

Comment 5: A comment was received which referenced the 2017 Guide to Crop Protection published by the Saskatchewan Ministry of Agriculture, which stated that the use of glyphosate for the use of "Crop Staging for Preharvest Applications" on the crops canary seed, mustard, chickpea, lupin and faba bean is registered under the URMULE program, and because of this "the manufacturer assumes no responsibility for herbicide performance. Those who apply glyphosate to chickpea, lupin, faba bean, canary seed, camelina or mustard do so at their own risk."

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

PMRA Response:

URMULE submissions reviewed by the PMRA assessed the health risk from glyphosate residues as a result of preharvest 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. No. 2015-1580), and lupin and faba bean (Sub. No. 2005-2797) on the Monsanto Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide (Reg. No. 27487) label. Residues in food commodities resulting from the desiccant 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.

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 oilseeds. MRLs are not established specifically for chickpea, dried lupin, and dried faba bean since residues on these crops are covered under the existing MRL for beans (4 ppm). Given

that the use on pearl millet grain is for animal feed only, an MRL is not established for this commodity. In addition, an MRL is not established for canary seed, since it is not a food use.

As mentioned above in the response to Comment 3, the dietary risk assessment conducted in the re-evaluation encompasses all registered food uses, including all registered desiccated food crops such as camelina, mustard, chickpea, lupin and faba bean.

Comment 6: A comment was received which states that the risk to human health from consuming crops that have been desiccated with glyphosate when moisture content is high is not mitigated by the proposed label amendments from the re-evaluation. It argues that there is no reasonable certainty that no harm to human health or future generations will result from dietary exposure to glyphosate, given that

1) **no label statements were proposed that would mitigate risk to human health from desiccation, and**
2) **any such label statements would not with reasonable certainty be effective because of the subjective content of any label and the unpredictability of the weather which can affect moisture content**

PMRA Response:

As indicated in response to Comment 2, directions for use on labels already indicate when applications should be made for preharvest use with specific plant growth stage (with associated pictographs) to describe precisely the application timing that corresponds to 30% moisture content.

Comment 7: A comment was received which referenced the aggregate risk assessment in PRVD2015-01 conducted for children 1 to less than 2 years old, examining post-application dermal exposure of glyphosate and incidental oral exposure (hand-to-mouth) from performing postapplication activities in treated lawns/turf + chronic dietary (food and drinking water). This aggregate exposure scenario initially assumed a glyphosate application rate of two applications with a seven day interval. At that application rate, the aggregate margin of exposure (MOE) for children (1 to < 2 years old) did not reach the target of 100. Therefore, refinements to the risk assessment were required.

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

PMRA Response:

The approach of conducting the aggregate risk assessment for children 1 to less than 2 years old exposed to glyphosate 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 1 to <2 years old exposed to glyphosate, the target MOE of 100 was not reached when aggregating chronic dietary exposure (food and drinking water) and postapplication exposure (dermal and incidental dietary) from entering turf treated with two applications, 7 days apart. As per SPN2003-04, "the PMRA believes, however, that the co-occurrence of high-end food, drinking water and residential exposure scenarios will often be impossible or, at best, highly unlikely." As such, the assumptions in the aggregate risk assessment were adjusted to represent a more realistic scenario, which included the use of the following:

- Canadian MRLs instead of American tolerances/Codex MRLs for barley, oats and wheat, since 99% of these crops consumed in Canada are produced in Canada;
- A typical application pattern of only one application at the maximum application rate; and
- a 7-day time-weighted average turf transferrable residue value.

Using the parameters described above, the refined aggregate risk assessment for children 1 to <2 years old resulted in a calculated MOE that reached the target MOE of 100. The target MOE of 100 was not reduced in the aggregate risk assessment.

This is **Exhibit "D"** referred to in the Affidavit of Mary Lou McDonald affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely, this 21st day of April, 2023

Bronwyn Roe

Commissioner for Taking Affidavits
Bronwyn Roe, LSO #63840R

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

Reference No. 2017-3047

September 29, 2022

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

Dear Ms. McDonald,

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

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

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

Legislative and Regulatory Framework for Decision

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

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

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

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

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

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

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

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

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

Section 3 of the *Regulations* states:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Summary of the Notice of Objection under Review

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

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

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

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

PMRA's Consideration of the Objections:

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

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

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

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

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

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

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

Pre-harvest use versus Desiccant use:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MRL exceedances do not equate to a health risk:

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

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

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

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[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?

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[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[1] 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[o] Refer to footnotes g, h

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

Health Canada's conclusions on the regulatory acceptability of glyphosate regarding the dietary risk from the consumption of crops that may be treated with glyphosate are consistent with those resulting from independent reviews by multiple scientific experts from other major pesticide regulatory authorities internationally[p][q]. 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

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[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?'**

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[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

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[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

Reference list

References cited in the Safe Food Matters Inc. Notice of Objection:

Benzil, C. 2012, provincial weed specialist with the Saskatchewan Ministry of Agriculture, as quoted in Angela Lovell, "Don't use desiccants to hasten maturity", Grainews (4 June 2012), online: <www.grainews.ca>

Bond, J. 2017. "Pulses Production Expanding as Consumers Cultivate a Taste for U.S. Lentils and Chickpeas." Amber Waves: The Economics of Food, Farming, Natural Resources, and Rural America. United States Department of Agriculture. Last accessed online May 26, 2022 at https://www.ers.usda.gov/amber-waves/2017/januaryfebruary/pulses-production-expanding-as-consumers-cultivate-a-taste-for-us-lentils-and-chickpeas/

Calles, T., del Castello, R., Baratelli, M., Xipsiti, M. and Navarro, D.K. 2019. 2016 The International Year of Pulses - Final report. Rome. FAO. 40 pp.

Cessna, A. J. Darwent, A. L. Townley-Smith, L. Harker, K. N. Kirkland, K. 2002. Residues of glyphosate and its metabolite AMPA in field pea, barley and flax seed following preharvest applications. Canadian Journal of Plant Science, 82(2): 485-489.

Cessna, A.J. Darwent, A. L. Townley-Smith, L. Harker, K.N. Kirkland, K.J. 2000. Residues of glyphosate and its metabolite AMPA in canola seed following preharvest applications. Canadian Journal of Plant Science, 80(2): 425-431.

Cessna, A.J. Darwent, A.L. Kirkland, K.J. Townley-Smith, L. Harker, K.N. Lefkovitch, L.P. 1994. Residues of glyphosate and its metabolite AMPA in wheatseed and foliage following preharvest applications. Canadian Journal of Plant Science, 74(3): 653-661.

Gabison Y 2014. The Dip That Roared: How Humus Conquered the US. June 20, 2014 Haaretz.com

Gaultier, J. Gulden, R. 2016. The science and art of dry bean desiccation. Crops and Soils, 49(4): 12-15.

Giles, D 2016. "Pea, lentil crops suffering from too much moisture as Sask. Harvest gets under way" August 4, 2016 Global News

Health Canada's Pest Management Regulatory Agency / Regulatory Operations and Regions Branch Compliance and Enforcement Report 2015-2016. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt_formats/pdf/pubs/pest/corp-plan/compliance-enforcement-2015-2016-conformite-application/compliance-enforcement-2015-2016-conformite-application-eng.pdf

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.

McNaughton, K.E. Blackshaw, R.E. Waddell, K.A. Gulden, R.H. Sikkema, P.H. Gillard, C.L. 2015. Effect of Application Timing of Glyphosate and saflufenacil as desiccants in dry edible bean (*Phaseolus vulgaris* L). Canadian Journal of Plant Science, 95(2): 369-375.

Mitra, T. 2017. "Glyphosate in chickpea, lentil and wheat bran." Last accessed online May 26, 2022 at http://www.tonu.org/2017/06/15/glyphosate-in-chickpea-lentil-and-wheat-bran/

Proposed Re-evaluation Decision PRVD2015-01, Glyphosate (13 April, 2015).https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-re-evaluation-decisions/2015/glyphosate/document.html

Re-evaluation Decision RVD2017-01, Glyphosate (28 April 2017). https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2017/glyphosate-rvd-2017-01.html

Saskatchewan Ministry of Agriculture, 2016. Crop Report for the Period August 30 to September 5, 2016.

Saskatchewan Ministry of Agriculture, 2017. Guide to Crop Protection for the Chemical Management of weeds, Plant Diseases, and Insects.

Science Policy Note SPN2003-03, Assessing Exposure from Pesticides, A User's Guide 28 July 2003). https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2003/assessing-exposure-pesticides-food-user-guide-spn2003-03.html

Science Policy Note, SPN2008-01. The Application of Uncertainty Factors and the *Pest Control Products Act Factor* in the Human Health Risk Assessment of Pesticides (29 July 2008).https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2008/application-uncertainty-factors-pest-control-products-act-factor-human-health-risk-assessment-pesticides-spn2008-01.html

Science Policy Note, SPN2014-01, General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments. Last accessed online July 4, 2022 at https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2014/general-exposure-factor-inputs-dietary-occupational-residential-exposure-assessments-spn2014-01.html.

Statistics Canada: Historical Supply and Disposition of Crop Years: 2010-2011 to 2015-2016 – Pulses and Special Crops. https://agriculture.canada.ca/en/market-information-system/rp/index-eng.cfm?action=pR&r=244&pdctc

Zhang, T. Johnson, E.N. Mueller, T.C. Willenborg, C.J. 2017. Early Application of Harvest Aid Herbicides Adversely Impacts Lentil. Agronomy Journal, 109(1): 239-248.

Zhang, T. Johnson, E.N. Willenborg C.J. 2016. Evaluation of Harvest Aids Application Timing for Lentil Dry Down. Weed Technology, 30: 629-638.

Zhang, T. 2015. Evaluation of Herbicides as Desiccants for Lentil (*Lens culinaris* Medik) Production. MSc thesis, University of Saskatchewan, Saskatoon.

Additional References cited in PMRA's Response to the NoO

Canadian Food Inspection Agency. 2017. Safeguarding with Science: Glyphosate Testing in 2015-2016. Last accessed online May 26, 2022 at https://inspection.canada.ca/food-safety-for-industry/food-chemistry-and-microbiology/food-safety-testing-bulletin-and-reports/executive-summary/glyphosate-testing/eng/1491846907641/1491846907985

Codex Classification of Foods and Animal Feeds | Agrisemantics Map of Data Standards www.fao.org/input/download/standards/41/CXA_004_1993e.pdf

Crop Grouping – IR-4 Project https://www.ir4project.org/fc/crop-grouping/

Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks, 1 August, 2000. https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html

Health Canada Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments, 28 August 2019. https://www.canada.ca/content/dam/hc-sc/documents/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/determining-study-acceptability-pesticide-risk-assessments/infonote-determining-study-acceptability-eng.pdf.

Kolakowski, B.M. Miller, L. Murray, A. Leclair, A., Bietlot, H. and van de Riet, J.M. 2020. Analysis of Glyphosate Residues in Food from the Canadian Retail Markets between 2015 and 2017. Journal of Agricultural and Food Chemistry, 68(18): 5201-5211.

PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products 28 July 2021. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/risk-management-pest-control-products.html

Proposed Maximum Residue Limit PMRL2021-10, Glyphosate. https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-maximum-residue-limit/2021/glyphosate/document.html

Regulatory Directive: Residue Chemistry Guidelines (DIR98-02). https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/1998/residue-chemistry-guidelines-dir98-02.html.

Science Policy Note SPN2003-04: General Principles for Performing Aggregate Exposure and Risk Assessments. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-

publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2003/general-principles-performing-aggregate-exposure-risk-assessments-science-spn2003-04.html.