

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.

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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

- 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*

- 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 dans 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 inclse? 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.

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

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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

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]

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/>
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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.

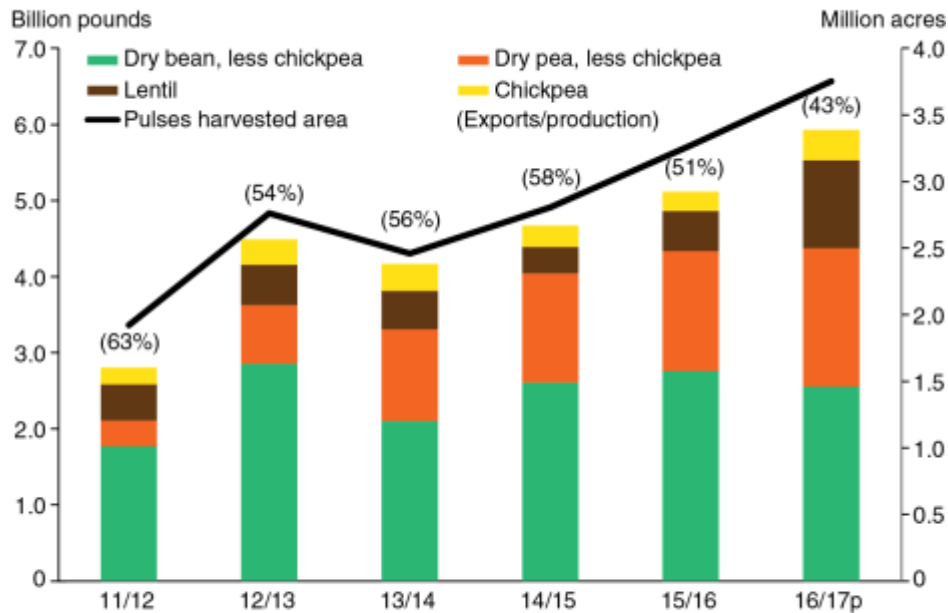
However this data is insufficient for purposes of reevaluating glyphosate. The consumption of chickpeas in the United States has grown at least 90% since 2010. Hummus is a dip made from chickpeas, and over a quarter of Americans reported in 2014 that they had the dip in the refrigerator. Consumer spending 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 --- thousand hectares ---	Area Harvested	Yield t/ha	Production	Imports	Total Supply	Exports	Total Domestic Use	Carry-out Stocks
	----- 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 - thousand hectares -	Area Harvested	Yield t/ha	Production	Imports	Total Supply	Exports	Total Domestic Use	Carry-out Stocks
	----- 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

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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 be 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

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

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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

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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

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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

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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 residues 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 in 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-

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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

