Notice of Objection to Re-assessment Decision RDV2017-01 on Glyphosate

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Introduction

Due to the time constraints imposed, this Notice of Objection, filed within 60 days from the decision date, shall focus on highlighting the deficiency and patchy and dated nature of the scientific references of the assessment and consultation document RDV 2015-01, allegedly the basis of the RDV2017-01 decision document, which essentially consists of confidential documents from the 1970 to 1990 originating from the industry, which is the main economic beneficiary of the decision – all factors that call into question the scientific rigor and independence of the approach.

The fact that the so-called "assessment" and "consultation" document, RDV 2015-01, took account of less than 1% of the abundant scientific literature on the health and environmental effects of glyphosate and glyphosate-based herbicides (GBH), published since the early 1970s, is highly problematic. Moreover, the fact that the massive structural increase in GBH sales - an essential element when examining the effects on health and the environment - does not even appear in the analysis constitutes a troubling omission. In the absence of a solid assessment document, the fact that those consulted were given the task of shedding light on the links between GBH and health problems, cancer, the environment and so on, based on recent scientific texts which were removed, with few exceptions, from the decision document without any rigorous, well-argued and explicit examination, raises doubts, at the very least, as to the rigor of the approach. The fact that the assessment scope still primarily targets glyphosate, even though GBH co-formulants are up to 1000 times more toxic than glyphosate (Mesnage et al., 2014), should have led to the systematic and express inclusion of an analysis of the various co-formulants in the assessment, and this is a major lacuna. The fact that the decision document RDV 2017-01 only proposes a minor modification of the labeling, placing the core of the health and environmental issues of GBH on farmers and consumers, as though labeling could thus clear pesticide companies and public authorities of their responsibilities, raises serious issues of democracy and of ethics.

These are, quickly described, some of the factors that lead to the belief that, based on these two documents, RDV2015-01 and RDV-2017-01, the PMRA lacks the scientific basis to be able to assert that they carried out “an in-depth review of glyphosate for public consultation purposes”. This therefore also raises doubts over its findings, that "products containing glyphosate do not pose an unacceptable risk to human health or the environment when used in accordance with the revised directions for use on the product labels." While our Notice of Objection focuses mainly on health issues and on occasion, on environmental issues, it raises the issue of "value" by seriously questioning the rigor and independence of these assessments in relation to the industries that are its main beneficiaries.

General observations

Let us review the summary of the PMRA decision on glyphosate (RDV 2017-01), which we have highlighted:

> "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." (PMRA, 2017:1)

1. Decision RDV2017-01 thus begins: "Health Canada's primary objective in regulating pesticides is to protect Canadians' health and their environment."

1.1 Health Canada's "primary objective", or obligation?

The primary objective of the Pest Control Products Act is "... to prevent unacceptable risks to individuals and the environment from the use of pest control products." (Government of Canada, 2002: 7). Now, "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." (Government of Canada, 2002: 7).

In addition, in the section on the Federal Government's duties, the Environmental Protection Act (1999) states that it MUST

j) protect the environment, including its biological diversity, and human health, from the risk of any adverse effects of the use and release of toxic substances, pollutants and wastes;

k) endeavour to act expeditiously and diligently to assess whether existing substances or those new to Canada are toxic or capable of becoming toxic and assess the risk that such substances pose to the environment and human life and health;
(Government of Canada, 1999: 4)

If Health Canada's obligations concerning protecting the health of the population are interpreted in light of these duties, then it must be concluded that the **first part** of the sentence, namely, "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", **must take precedence.** Indeed, it would be improper and contrary to the spirit of the laws to imply that the second part of the sentence, namely "taking into account its conditions or proposed conditions of registration", could prevail, or render its content void, and even invalidate the first part of the sentence.

Paradoxically, however, this is indeed the interpretation arising from decision RDV2017-01, since the actual registration conditions and the DRV201501 assessment on which it is based in no way support the assertion that "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", since the work has not been done in accordance with current professional practices and scientific requirements.

Indeed, recalling that the PMRA decision, RDV2017-01, is based on the outcome of the PMRA's so called "extensive re-examination of glyphosate for public comment (PRVD2015-01), in which the PMRA had concluded that "the products containing glyphosate do not present unacceptable risks to human health or the environment", while adding "when used according to the revised product label directions".

2. Now how can the PMRA seriously claim to have a "reasonable certainty that no harm to human health," but also to "future generations or the environment will result from exposure to or use of the product", when:

2.1. Decision document RDV2017-01 essentially reproduces document PRVD2015-01, which ignores most scientific literature on the effects of glyphosate on human health published in the last ten years

The PMRA's assessment, the findings of which are published in report PRVD2015-01 of 2015, is based on 32 pages of studies and information provided by the industry, and thus kept secret without any independent, scientific peer assessment, whereas "the voluminous scientific literature published on the subject", to use the terms of this PRVD2015-01 report, is limited to about fifteen pages of published studies and information.

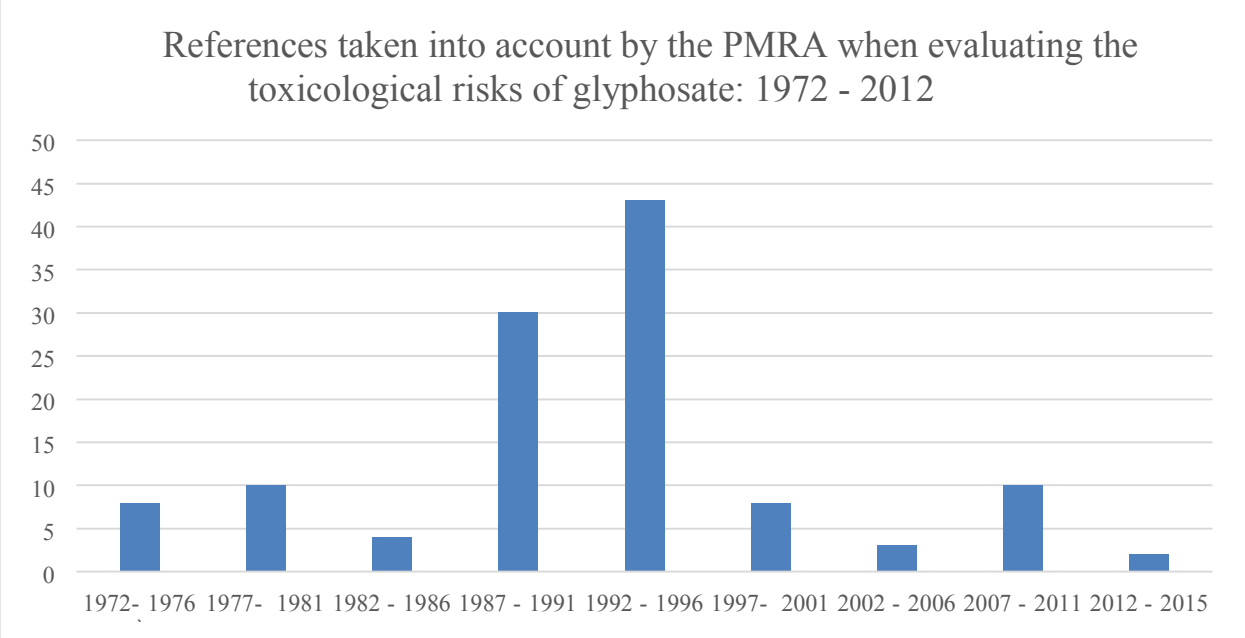
2.2. Glyphosate, human health and future generations: **a toxicological hazards assessment riddled with gaps**

In document PRVD2015-01, the health impact assessment is approached in three sections, adopting the categories given, those of the "toxicological hazards", the "occupational risks" and the "dietary risks".

The component concerning the PMRA's assessment of the "toxicological hazards" is based on 118 references (4 pages) submitted by companies that are thus unpublished. Of the other 7 references, supposedly published, the authors and places of publication are not identified[1].

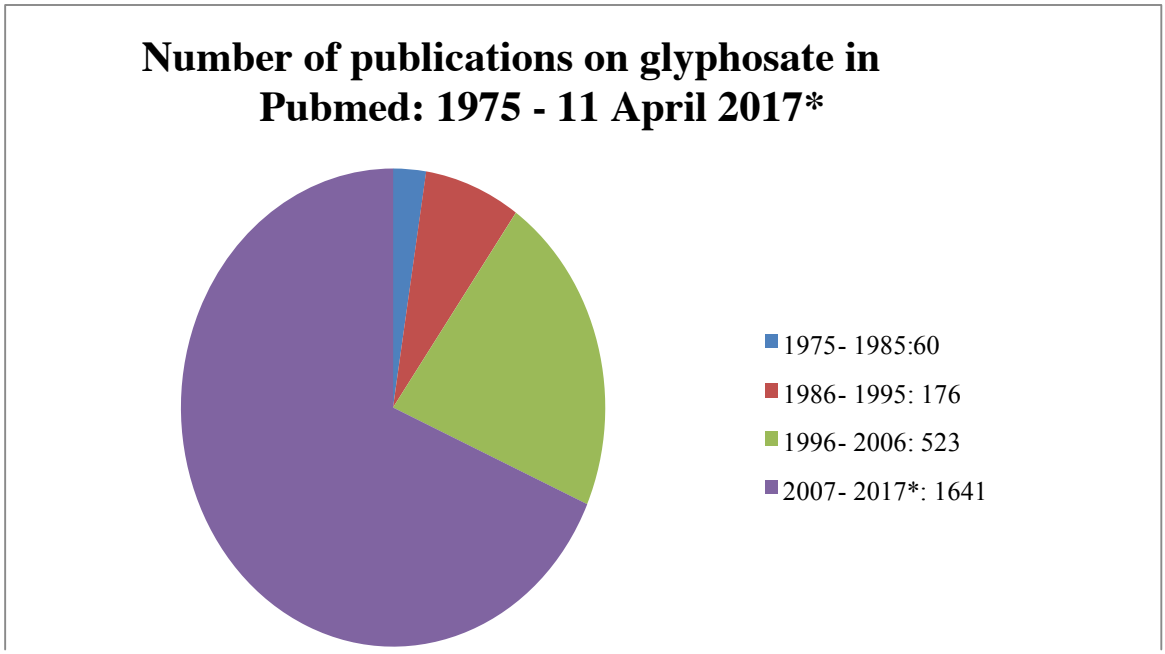
These considerably outdated references do not correspond to the current state of knowledge. In fact, 80.5% of the references in this assessment component were produced before 1996, that is, 22 references between 1972 and 1986 and, the majority (73) between 1987 and 1996, a period of sustained activity on the part of the industry aimed at introducing genetically modified (GM) crops into Canada (mainly maize, soybeans and canola) in 1996, GM crops designed to absorb glyphosate-based herbicides without dying. It is doubtful whether these studies, conducted by pesticide producers prior to the marketing of GM crops that has caused GBH usage to explode, are likely to shed light on the impact of these herbicides on human health, with any independence and credibility, and with solid scientific assessments in the medium and long term.

[1] This Notice of Objection is a translation of the original paper written in French. Therefore, we have worked with the French version of the assessment published by the PMRA. We just noticed that the English version of the assessment states that: "Only published studies that are cited in the PRVD are listed below; a full list of published information considered in the re-evaluation is available upon request." (PMRA, 2015: 260), a note that was missing from the French version (ARLA, 2015: 277).



It is thus on the basis of 95 references submitted by companies dating from over 20, 30 or 40 years ago, that the "toxicological hazards" section of document PRVD2015-01 purported to conclude that "products containing glyphosate do not pose an unacceptable risk to human health or the environment" or that " Products containing glyphosate acid are unlikely to affect your health... " (PMRA, 2015: 2), which, given the rapid evolution of the research on the health impacts of certain chemical substances and chemical cocktails, does not in any way correspond to scientific requirements. Moreover, to judge the seriousness of the PMRA's "review", it is still necessary to take account of the current state of knowledge in this area.

Yet the scientific literature on glyphosate and GBH in relation to health and the environment is particularly abundant. This is evidenced in a Pubmed (US National Library of Medicine) review of scientific papers on glyphosate, facilitating the identification of 2,400 references (from 1975 until April 11, 2017, the research date), of which the majority, 68% (1641 references) were published in the last 10 years - while the “toxicological hazards” component of the PMRA's 2015 document is based solely on 12 references for the 2007-2012 period.



The marked increase in scientific publications on glyphosate and GBH is not exclusive to biomedical literature. A review of references to glyphosate in the Agricola bibliographic database (United States Department of Agriculture, National Agricultural Library) shows that of the 5504 references published between 1972 and 15 June 2007, the date of the research, 41% of the references (2254) have been published since 2007, that is, in the last 10 years.

As such, the 118 references in the "toxicological hazards" section of document PRVD2015-01, the cornerstone to the health issues of the decision document PRVD2017-01, correspond to less than 0.049% of the 2,400 scientific articles identified in Medline and less than 0.006% if one excludes industry documents and articles with unidentified authors and places of publication.

This is all the more critical as this PMRA document, PRVD2015-01, allegedly forms the basis for the decision (PRVD2017-01) to authorize glyphosate, and thus glyphosate based herbicides for over another 14 years, that is, until around 2031 – based on references provided mainly by the industry, references that will by then be up to 50 to 60 years old.

Assessment of the Occupational Risks from Glyphosate or GBH?

It may be argued that the toxicological hazards section is only one of the three health-related components. However, if one examines the "Assessment of the Occupational Risks" section, the occupational risk assessment is found to be based only on one industry document from 2001, 7 unpublished references from 1995 to 2008 and on a single EPA reference published in 2012, entitled "Standard Operating Procedures for Residential Pesticide Exposure Assessment", which is not an assessment of the major occupational risks, that is, those affecting farmers and their families, agricultural workers and technicians, but concerns the procedures for residential pesticide exposure assessment, which, in comparison to glyphosate-based herbicides, represent a small fraction of GBH usage.

This section of RVD2015-01 thus does not support any conclusion that the occupational risk assessment was conducted, nor that it was done adequately and rigorously, from credible sources, another major gap in the assessment, which in no way allows to determine the risks.

Assessment of the Dietary Risks

In document RVD2015-01, the dietary risk assessment is once again based exclusively on 16 pages of references, that is, nearly 340 unpublished industry-supplied documents from 1971 to 2012, and 7 references from published information.

Here, the references submitted by the glyphosate-based herbicide producers make up 98% of the documents examined for the dietary risk assessment, while these confidential documents cannot be subject to any independent scientific counter-assessment. A review of the titles of the documents provided by the companies demonstrates that a very large number of those were filed as part of a product registration application, and thus aimed at determining the presence and residue levels of glyphosate in specific crops.

Once again, approximately 70% of the documents date from before 2000. As for the 2007 and 2008 reference period, this is almost exclusively related to DuPont de Nemours and Compagny. Several references are also found to be related to a single study, while others are USEPA memos concerning labeling changes, residue detection methods, germination studies or even applications by firms for exemption from glyphosate residue studies. Several documents are clearly seeking acceptance of the presence of GBH residues, such as Roundup, or seek to establish so-called "acceptable" glyphosate residue limits, such as those filed by Monsanto in 1974[2].

While the dietary risk assessment should logically cover all food-related GBH usage (cereals, legumes, vegetables, fruits, milk, eggs, and so on) and exposed animals, as well as water, based on the most up-to-date data, while being part of a rigorous analysis of the increased spraying and the factors behind this increase, this document makes very little reference to it.

Residues in food

Among these industry-provided references, only around thirty documents, one-third of which are dated from 1973 and 1974, relate to the presence of residues in meat (goat, pork, chicken, beef), milk and eggs. The information dates back almost 45 years – which, by the end of the period the PMRA wants to authorize, will be 60 years old!

It is true that, until recently, Canada characteristically lacked a biomonitoring program and epidemiological studies of GBH. According to Health Canada's "*Human Biomonitoring of Environmental Chemicals*" program, glyphosate was not included in the National Chemical Residue Monitoring Program, although the Canadian Food Inspection Agency (CFIA) "carried out

[2] "Information to support the establishment of permanent tolerances and label registration for the use of Roundup as a pre-plant herbicide on corn (all types), soybeans, wheat and other small grains. Section E: Residue Removal + Section F: Proposed tolerances + Section G: Summary and conclusions (reasonable grounds in support of the petition for residue tolerance)" (ARLA, 2015: 285).

a total of 31,306 tests for pesticide residues on 10,589 monitoring samples of domestic and imported foods of animal and plant origin (2013-2014)".

It was not until 2017, after several years of sustained requests from Canadian citizens to obtain data on glyphosate residues in food, that the first data on glyphosate residues was finally published. It could then be seen that nearly 30% of the 3,188 samples analyzed by the CFIA were contaminated. Specifically, 31.7% of cereals and 30.7% of food for infants, a particularly vulnerable population, contained glyphosate residues (CFIA, 2017). In addition, 1.3% exceeded the Maximum Residue Limit (MRL) for food, specifically grains with 3.9% of samples exceeding the MRL, as shown in the table below (CFIA, 2017).

Program	Food Type	# Samples Tested	% Samples with Glyphosate Residues Detected	% Samples with Glyphosate Residues above MRLs
National Chemical Residue Monitoring Program	Fresh fruits and vegetables	317	7.3%	0%
	Processed fruits and vegetables	165	12.1%	0%
Targeted Surveys	Grain products	869	36.6%	3.9%
	Juice and other beverages	496	16.3%	0.2%
	Bean/pea/lentil products	869	47.4%	0.6%
	Soy products	263	11.0%	0%
Children's Food Project	Infant cereal	82	31.7%	0%
	Infant food	127	30.7%	0%
	TOTAL	**3,188**	**29.7%**	**1.3%**

CFIA, 2017

Analysis of the effects of GBH in food and water should involve an examination of the successive increases in authorized residue limits as a result of increased spraying - and the increasing exposure, including airborne, to various dietary and water sources and specifically the issue of residues in food (Myers et al., 2016).

Surprisingly, assessment document RVD2015-01 and decision document RVD 2017-01 are not in the least interested in the marked increase in GBH uses and spraying, leading to a massive and continuous GBH presence in the environment, in food for humans and animal feed, and in water.

The increasing presence of GBH in water

In the case of water, document RVD2015-01, in its section on assessing the dietary risks, which was also intended to address the risks to drinking water, refers to only two references, dating back to 1974 and 1979, concerning Roundup residues in water. As such, this means that the issue of the contamination of drinking water and its consumption is completely ignored.

Given the dramatic increase in the amount of GBH released into the environment since the 1970s and its effects on the increased contamination of water supplies, an in-depth re-assessment should have been required. Indeed, in Quebec, there has been an increase in the presence of glyphosate and AMPA in the water of rivers in arable areas.

As such, in the watershed areas in maize and soybean-based agricultural zone in Quebec, the detection frequency of glyphosate and AMPA from 2001 to 2014 was 88% in 2014, according to the Giroux studies (in 2010 and 2015) and Giroux and Pelletier (in 2012), as shown in the graph below.

Increase in the presence of glyphosate and AMPA in the water of certain rivers in Quebec

Glyphosate and AMPA detection frequency in Quebec from 2001 to 2014

Giroux (2010 and 2013; Giroix and Pelletier (2012)

Chronic aquatic life criteria

Pesticides	CVAC Québec (µg/l)	CVAC Canada (µg/l)
Atrazine and metabolites	1.8	1.8
Glyphosate	65	800

This chart also examines the incredible difference in chronic toxicity criteria for aquatic life, which is 800 µg/l in Canada, 12 times more than in Quebec, where it is 65 µg/l!

These results deserve to be put into perspective with the results of a 2-years study, on 200 rats in 4 subgroups, on " The health effects of a Roundup-tolerant NK603 genetically modified (GM) maize (from 11% in the diet), cultivated with or without Roundup application and Roundup alone (from 0.1 ppb of the full pesticide containing glyphosate and adjuvants) in drinking water", a study published in Environmental Sciences Europe (Séralini et al., 2014).

This study, which was not designed as a carcinogenesis study, constitutes, in the words of the authors, "a follow-up investigation of a 90-day feeding study conducted by Monsanto in order to obtain commercial release of this GMO, employing the same rat strain and analyzing biochemical parameters on the same number of animals per group as our investigation. (It) thus represents the first chronic study on these substances, in which all observations (including tumors) are reported chronologically." (CRIIGEN: criigen.org/ogmCategory/6/display/Info_Vivo- 2017).

Taking into account the importance of this study conducted by an independent team, specifically on the potential health impacts of glyphosate in water, the terms of the study state: "For each sex, one control group had access to plain water and standard diet from the closest isogenic non-transgenic maize control; six groups were fed with 11%, 22%, and 33% of GM NK603 maize either treated or not treated with R. The final three groups were fed with the control diet and had access to water supplemented with respectively 1.1×10^{-8}% of R (0.1 ppb or 50 ng/L of G, the contaminating level of some regular tap waters), 0.09% of R (400 mg/kg G, US MRL of 400 ppm G in some GM feed), and 0.5% of R (2.25 g/L G, half of the minimal agricultural working dilution)" (Séralini et al, 2014).

For the results, the authors state that:

"Biochemical analyses confirmed very significant chronic kidney deficiencies, for all treatments and both sexes; 76% of the altered parameters were kidney-related. In treated males, liver congestions and necrosis were 2.5 to 5.5 times higher. Marked and severe nephropathies were also generally 1.3 to 2.3 times greater. In females, all treatment groups showed a two- to threefold increase in mortality, and deaths were earlier. This difference was also evident in three male groups fed with GM maize. All results were hormone- and sex-dependent, and the pathological profiles were comparable. Females developed large mammary tumors more frequently and before controls; the pituitary was the second most disabled organ; the sex hormonal balance was modified by consumption of GM maize and Roundup treatments. Males presented up to four times more large palpable tumors starting 600 days earlier than in the control group, in which only one tumor was noted. These results may be explained by not only the non-linear endocrine-disrupting effects of Roundup but also by the overexpression of the EPSPS transgene or other mutational effects in the GM maize and their metabolic consequences."
(CRIIGEN: criigen.org/ogmCategory/6/display/Etude-In-Vivo-fr. 2017)

Concerning the results more specific to water, the article states: "It was previously known that G (Glyphosate) consumption in water above authorized limits may provoke hepatic and kidney failure [33]. The results of the study presented here clearly indicate that lower levels of complete agricultural G herbicide formulations, at concentrations well below officially set safety limits, can induce severe hormone dependent mammary, hepatic, and kidney disturbances." (Séralini et al, 2014).

The authors thus conclude, "Our findings imply that long-term (2 years) feeding trials need to be conducted to thoroughly evaluate the safety of GM foods and pesticides in their full commercial formulations."

If, from 0.1ppb, this study shows that Roundup is highly tumorigenic, causes hormone-dependent tumors and other hormonal imbalances, as well as toxicity to the liver and kidneys, what is to be thought of the standards set by the drinking water regulations which are 210 µg/1 in Québec, or 2,100 times higher than one of the three doses used in this study which is corresponding to the European standards of 0.1 ppb ? What is to be thought of the Health Canada recommendations setting them at 280, or 2,800 times higher, and those of the United States, which sets them at 700, or 7,000 times higher ?

Drinking water standards: Quebec, Canada, USA, EU:
Atrazine/metabolites and glyphosate

Pesticides	Quebec Standards [1] (µg/1)	Canadian Recommendations [2] (µg/1)	USA Standards [3] (µg/1)	**European Standards [4] (µg/1)**	Difference between Québec and European standards
Atrazine and its metabolites	3.5	5	3	0.1	350
Glyphosate	**210**	280	700	0.1	2100

[1] Regulation on Québec drinking water quality: http://www.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=3&file=/Q_2/Q2R40.HTM, accessed March 14, 2016
[2] Health Canada: http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/sum_guide-res_recom/index-eng.php, accessed December 6, 2016
[3] EPA: www.epa.gov/ground-water-and-drinking-water/table-regulated-drinking-watercontaminants#Organic, accessed January 15, 2017
[4] EC Directive 98/83of the European Council, http://www.ineris.fr/aida/consultation_document/1017, accessed April 20, 2017

This study is to be placed in the perspective of two others by Mesnage et al., one of which, focused on assessing the active ingredient in 9 of the best-selling pesticides in the world (3 herbicides, 3 insecticides and 3 fungicides), showed that the co-formulants in 8 of the 9 cases are up to 1,000 times more toxic (Mesnage et al., 2015). Another *in vivo* study of chronic liver toxicity showed that doses of 0.1ppb (equivalent to 4ng/kg/day of a Roundup dose) administered into rat water had significant effects (Mesnage et al., 2017). Of the 1906 hepatic proteins tested, 214 were significantly impaired, reflecting a proliferation in peroxisomes, steatosis and necrosis, and, of the 673 metabolites analyzed, 55 were significantly altered, reflecting lipotoxic conditions, oxidative stress and hepatotoxicity (Mesnage et al, 2017).

In this context, can the PMRA ignore the few studies that enable evaluation of these effects, and can it then conclude, without any in-depth scientific review, that "Dietary risks from food and water are not of concern." (PMRA, 2015, 2017: 4)?

How can the structural increase in the world's best-selling pesticide be ignored?

These questions about the toxicological and occupational dangers and the food and water risks are all the more important in view of the exponential increase in glyphosate based herbicides, which are by far the best selling of any pesticide globally. Failure to take account of this is a major and unjustifiable lacuna in this assessment of the health and environmental risks of GBH.

Foucart and Horel, Le Monde journalists, stressed that "For more than forty years, glyphosate has been used in the composition of no less than 750 products, marketed by about 100 companies, in more than 130 countries". Glyphosate, added the journalists, "is Monsanto's

keystone. Between 1974, when it was placed on the market, and 2014, its use increased from 3,200 to 825,000 tonnes per year" (Foucart and Horel, 2017). Spraying would thus have multiplied 258 times on areas that did not increase in nearly such an exponential way...

Considered by the industry and by regulators as the main component of Roundup, which itself warrants serious implications (Mesnage et al., 2014), glyphosate, "the flagship product of one of the world's most famous companies: Monsanto" constitutes "the Leviathan of the agrochemical industry," to quote Foucart and Horel (Foucart and Horel, 2017).

Since 1974 in the USA, "over 1.6 billion kilograms of glyphosate active ingredient have been applied, or 19 % of estimated global use of glyphosate (8.6 billion kilograms). Globally, glyphosate use has risen almost 15-fold since so-called “Roundup Ready,” genetically engineered glyphosate-tolerant crops were introduced in 1996. Two thirds of the total volume of glyphosate applied in the U.S. from 1974 to 2014 has been sprayed in just the last 10 years. The corresponding share globally is 72%" (Benbrook, 2016).

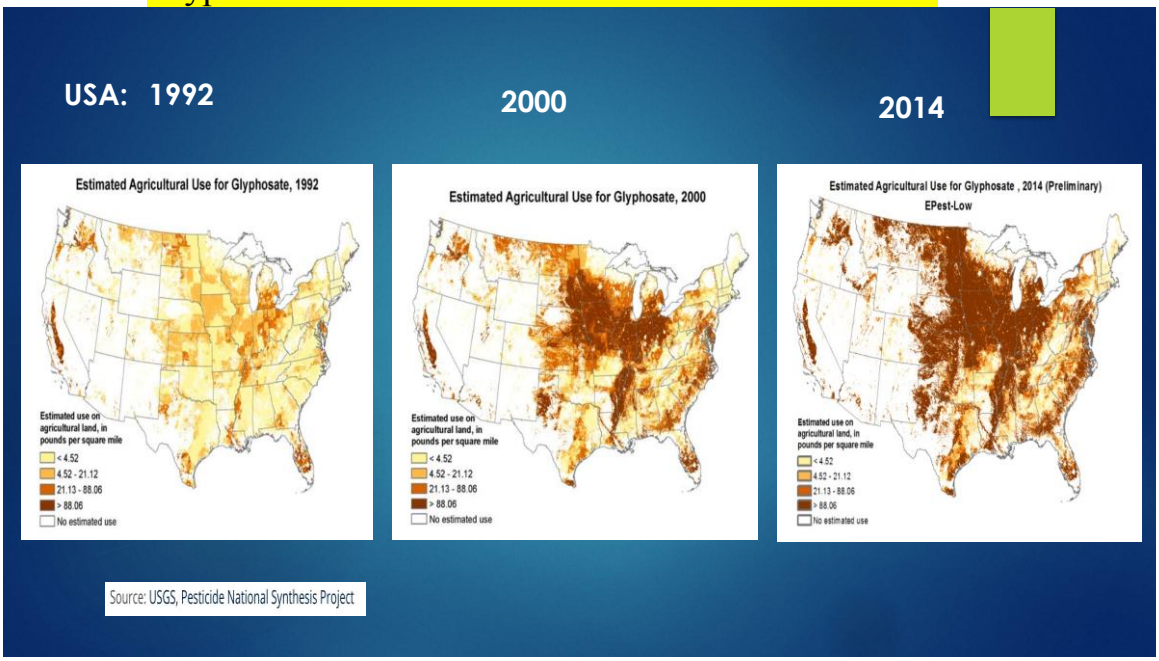
Benbrook stresses that this increase in GBH is global: "In 2014, farmers sprayed enough glyphosate to apply ~1.0 kg/ha (0.8 pound/acre) on every hectare of U.S.-cultivated cropland and nearly 0.53 kg/ha (0.47 pounds/acre) on all cropland worldwide." (Benbrook, 2016)

Although this is American data, we cannot ignore the fact that we import a large part of our food from the United States, especially from California. Furthermore, as compared to the United States and Europe, Canadian agriculture consumes mainly herbicides, this suggesting that GBH predominates, which is confirmed by the 25 million kilos of glyphosate, the active ingredient, sold in Canada in 2011, which is by far the best-selling pesticide (Santé Canada, 2012: 21).

In Quebec, GBH multiplied 5.3 times between 1992 and 2014, to constitute 42% of all pesticides in 2014, according to the 2014 Quebec pesticide sales figures (MDDELCC, 2016). The complete, detailed glyphosate sales records, by region, are thus essential in order to enable monitoring the development thereof, and even to identify the different GBH formulations that do not present the same toxicity (Mesnage et al., 2014), in order to target those that are most sold and those that present the greatest risk. Independent research teams could thus have confidential access to this data, for counter-expertise purposes, to monitor public health and the state of the environment.

Thus, the potential impacts of this increase in GBH on all food and water resources cannot be ignored, as the PMRA appears to have done in both its documents. All the more so, as these crops with GBH are largely concentrated in the United States, in the north-central part of the country near the Great Lakes, as evidenced by these maps.

Glyphosate Based Herbicides: 1974-2014 USA X 15



Given this significant increase in GBH spraying, concentrated in the United States over the past 10 years, and given the increasing spraying over the highly agricultural regions in Canada (the Plains, Ontario and Quebec), a significant portion of which flows into the Great Lakes and the St. Lawrence, it is difficult to understand why a so-called scientific assessment aimed at approving GBH for an additional 15 years, as the PMRA intends for glyphosate, ignores an examination of such a potential impact on food and water, but also on health and the environment, in addition to ignoring the recent literature that takes account of it. Furthermore, how can such an evaluation ignore the structural factors contributing to this exponential growth of GBH spraying, an essential element before extending the registration of glyphosate for 15 years...

Factors in this structural increase in GBH

This dramatic increase in GBH sales is largely due to the massive adoption of genetically modified seeds since 1996: maize, soybeans, canola and cotton, concentrated mainly in the United States, Brazil, Argentina and Canada. According to Benbrook "Genetically engineered herbicide-tolerant crops now account for about 56% of global glyphosate use. In the US, no pesticide has come close to such intensive and widespread use" (Benbrook, 2016).

Benbrook adds that this increase in GBH affects virtually the entire planet. "This is likely the case globally, but published global pesticide use data are sparse. Glyphosate will likely remain the most widely applied pesticide worldwide for years to come, and interest will grow in quantifying ecological and human health impacts." (Benbrook, 2016: 3).

This sharp increase in glyphosate-based herbicides has not only resulted from the introduction of GM crops since 1996, but also from the sharp increase in the authorized uses of

HBG by public bodies. As such, in Canada, GBH use is permitted for virtually all GM crops: soybeans, corn and canola. Yet the maximum annual dose permitted by the regulatory authorities is 20 to 25% higher than in non-GM crops.

In agriculture, GBH are also used in cereals, legumes, berry crops -three important production and export sectors - and also in market gardening. These uses now extend to all cultivation periods - before sowing, at the time of emergence, at pre-harvest and at post-harvest - leading to an almost continuous GBH presence in agriculture, and thus in the environment. During pre-harvest, they are used specifically for desiccation of cereals and legumes, resulting in increased residues. In addition, the increase in GBH-resistant plants, especially with GM crops, now at more than 30 resistant plants, has led to the use of even more GBH.

Finally, in Canada, the PMRA authorizes each year new products containing glyphosate, which have gone from 169 to 189 products between May 2012 and April 2017, while 13 others are currently pending approval.

Glyphosate and cancer

The PMRA's 2017 decision document denigrates the IARC study on carcinogenicity, *inter alia* because it does not take account of the manufacturers' studies ... (PMRA, 2017: 19). It is true that the weight of the industry in assessment bodies, as reflected in these PMRA documents, is also felt in European bodies, according to the report by the Corporate Europe Observatory (CEO), a Brussels-based NGO and a specialist on influencing strategies exercised in European institutions, according to whom "Almost half the experts sitting on European Food Safety Authority (EFSA) panels have a financial conflict of interest with the industrial sectors regulated by the agency." (Foucart, 2017).

An important document by an American expert, calling into question the issues of transparency and rigor of these bodies in the case of GBH, seriously questions the very results of the studies on which the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) based their assertion of the absence of any glyphosate danger, bodies which, according to its author, CJ Portier, underestimate the reality.

In a letter addressed to the President of the European Commission, Jean Claude Juncker, on 28 May 2017, US biostatistician and toxicologist Cristopher J. Portier, Ph.D., former Director of the Environmental Toxicology Program at the NIEHS, warned the European Union that, after having reviewed dozen of studies on the link between glyphosate and cancers, studies that served as references for the European Food Safety Agency (EFSA) and the European Chemicals Agency (ECHA) to exonerate the molecule, he found 8 statistically significant tumor sites that had never been noted by the European authorities (Portier, 2017).

Cristopher J. Portier, who is also the "Former Director US National Center for Environmental Health, Former Director, US Agency for Toxic Substances and Disease Registry, Former Associate Director, US National Institute of Environmental Health Sciences, Former Associate Director, US National Toxicology, Program Fellow, American Statistical Association, Fellow, International Statistics Institute" stresses in this letter that "The raw data for the animal cancer studies for glyphosate have been released, and a reanalysis of this data shows eight instances where significant increases in tumor response following glyphosate exposure were not included in the assessment by either EFSA or EChA. This suggests that the evaluations applied to the

glyphosate data are scientifically flawed, and any decisions derived from these evaluations will fail to protect public health. I ask that the evaluations by both EFSA and EChA be repeated for all toxicological endpoints and the data underlying these evaluations be publicly released."

Mr. Portier states that “Both EFSA and EChA (in their proposal of the dossier submitter) failed to identify all statistically significant cancer findings in the chronic rodent carcinogenicity studies with glyphosate.” “Thus, of the 21 positive tumor findings in Table 1 and Table 2, BfR, in their original submission, had only identified 20%,” adding, “After the IARC Monograph review and after recognizing that there were other studies with positive results in this data that were not reported by the Glyphosate Task Force, it is difficult to understand why BfR, EFSA and EChA failed to re-evaluate all of the available data using an appropriate trend test.”

As a result, Dr. Portier adds, "I am concerned about other reproductive toxicity and endocrine disruptions," and points out that several important elements were not considered:

"Finally, in our previous letter, several major questions were raised in the final assessments and should be repeated appropriately. These are:

- the classification of the human evidence as "very limited" is not a valid characterization under the CLP guidelines, and fails to properly address the strength of the available evidence;
- both EFSA and EChA dismissed positive findings because they fell inside of the range of the historical controls (this is an improper use of historical control evidence);
- both EFSA and EChA compared findings across different strains and different study durations to conclude that studies were inconsistent (this is not scientifically justifiable);
- both EFSA and EChA characterize the evidence for genotoxicity as negative, yet a careful review of the evidence released by EFSA and the open scientific literature suggest there are many guideline and non-guideline studies demonstrating genotoxicity.

Christopher J. Portier concludes, “The glyphosate hazard classification appears to have been a good example of how lack of transparency regarding the scientific evidence that underlies important public health decisions can erode public trust and raise concerns.”

We attach Christopher J. Portier’s letter to the President of the European Commission, Mr. J-C Juncker, to this Notice of Objection.

In conclusion, we recall that the Commission asked its two agencies, ECHA and EFSA, to evaluate the biostatistician's allegations carefully and in detail before proposing to authorise GBH for 10 years.

In light of these new analyzes, specifically by an eminent specialist in the field, it would be unwise for the PMRA and other Canadian bodies to refuse to suspend or halt the decision to extend registration of glyphosate and glyphosate-containing products for 15 years, in order to carry out a complete and independent re-assessment worthy of the name.

Conclusion

Since the technical analysis tools have become considerably refined and more accurate, and since scientific knowledge concerning toxicology and the environmental and health impacts of chemicals has progressed tremendously, not only since the commercialization of many pesticides but more particularly over the past 15 years, it would be unjustifiable for both the Canadian public and the reputation of its public bodies, that the PMRA and Health Canada continue to make of the document PRVD2015-01, the cornerstone of their re-assessment decision, which they submitted as being final.

In terms of health, in particular, how can it be justified that the 118 references of the "toxicological hazards" section of the document PRVD2015-01, serving as the cornerstone of the health issues in the decision document PRVD2017-01, derive almost entirely from the industry and are therefore unpublished, while the authors and places of publication of the other 7 references supposedly published are unidentified? Inasmuch as the scientific work is based on peer-reviewed studies published in scientific journals, these references in the PMRA's document PRVD2015-01 correspond to less than 0.049 of the 2,400 scientific articles identified in Medline from 1975 to April 2017, and less than 0.006, if one excludes industry documents and articles with authors and places of publication not indicated.

As for the occupational risk assessment, it is based only on 1 industry paper submitted in 2001, 7 unpublished references from 1995 to 2008 and 1 single published reference. The dietary risk assessment in document RVD201501, is based exclusively on 16 pages of references, that is, nearly 340 industry supplied documents dating from 1971 to 2012, and thus confidential and unpublished, and 7 published information references. Again, about 70% of the documents date from before 2000. It is true that, in 2010, the announcement to re-assess glyphosate was already stating that "at this time no new data requirements have been identified" (ARLA, 2010: 2)…

Given the considerable weight, to put it mildly, of industry-derived references in PMRA document PRVD2015-01, confidential documents, we recall, not subject to independent counter-assessment, and in the almost total absence of clearly identified scientific articles, to dare to claim at the opening of document PRVD2017-01, that "*Health Canada's primary objective concerning pesticide regulation is to protect the health and safety of Canadians and their environment*. " is tantamount to deception.

In light of the abundant scientific literature on glyphosate, and in light of the above findings, the PMRA, which took account in its assessment document of only a tiny fraction of the scientific articles in the field, essentially those before 2000, cannot claim to have carried out a rigorous scientific assessment, nor claim that its document PRVD2015-01, attests to an "in-depth review of glyphosate for public consultation purposes," as alleged at the beginning of decision document PRVD2017-01.

Even less can it claim to have "reasonable certainty that no harm to human health, to future generations or to the environment will result from exposure to the product or the use thereof". In fact, these documents do not constitute any sound scientific basis for enabling it to affirm either

that “products containing glyphosate do not pose an unacceptable risk to human health or the environment” or that “Products containing glyphosate acid are unlikely to affect your health when used according to label directions" (PMRA, 2017: 3).

The assessment of glyphosate products and Act's Preamble

The assessment of glyphosate based products and the renewal of its registration for the next 15 years contravene several elements of the Pest Control Products Act’s Preamble (Government of Canada, 2002), which we have highlighted in bold.

In particular, the Preamble states:

> “WHEREAS the availability and use of pest control products pose potential **risks, both directly and indirectly, to the health, safety and well-being of individuals in Canada and to the environment;**
>
> WHEREAS **the goals of sustainable pest management are to meet society’s needs for human health protection**, food and fibre production and resource utilization and **to conserve or enhance natural resources and the quality of the environment for future generations**, in an economically viable manner;
>
> WHEREAS Canada and the provinces and territories have traditionally administered complementary regulatory systems **designed to protect individuals and the environment, including its biological diversity, from unacceptable risks posed by pest control products**, and it is important that such an approach be continued in order to achieve mutually desired results efficiently, without regulatory conflict or duplication;
>
> **WHEREAS it is in the national interest that the primary objective of the federal regulatory system be to prevent unacceptable risks to individuals and the environment from the use of pest control products,**
>
> 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,
>
> 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 impact or pollution of the environment,**
>
> **in assessing risks to individuals, consideration be given to aggregate exposure to pest control products, cumulative effects of pest control products and the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors,**

> pest control products be regulated in a manner that supports sustainable development, being development that meets the needs of the present **without compromising the ability of future generations to meet their own needs,**
>
> the federal regulatory system be designed **to minimize health and environmental risks posed by pest control products** and to encourage the development and implementation of innovative, sustainable pest management strategies, for example by facilitating access to pest control products that pose lower risks, and **encouraging the development and use of alternative, non-toxic, ecological pest control approaches, strategies and products,"**
> (Government of Canada, 2002: pp.1 - 3)

Finally, it should be noted that, in addition, the Pest Control Products Act is meant to be concerned with the "Protection of future generations", since:

> "4.1 For greater certainty, protection and consideration afforded to children in this Act shall also extend to future generations. (Government of Canada, 2002: 8)

Ultimately, what best describes the health and environmental risk assessment conducted by the PMRA is probably this proverb:

> "*It's very hard to find a black cat in a dark room…especially if you're not looking for it…*"

This is why the conditions, grounds and rationale for this PMRA "health and environmental risk assessment" of GBH results in putting at stake human health, specifically vulnerable populations, and the environment, and thus future generations, which is fundamentally contrary to the elements of the Act cited above. As a result, the PMRA's decision to renew the registration of glyphosate herbicides for the next 15 years is unacceptable.

Given the above, we request:

1. The suspension of the renewal approval of glyphosate.

2. A thorough, independent, rigorous and transparent scientific re-evaluation of the toxicity of the formulations and not only of the so-called active principle, glyphosate.

3. For the PMRA to dissociate itself from agrochemical industry interests, and divest themselves of the influence of the latter, so as to demonstrate the ethical and scientific rigor that Canadians expect.

Please confirm your receipt of this Notice of Objection. We hereby request a detailed response to the concerns expressed in this Notice, as well as to the requests made above.

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