

Results of the OCMOH Action Plan on Glyphosate

**A report prepared for the Acting Chief Medical Officer
of Health**

Department of Health
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Corrigenda

Revised version published September 2, 2016: editorial changes were made to pages 5, 17 and 33 to more clearly explain the difference between the work of NCCEH and CAREX Canada, and to clarify that the results of their work will not be recommendations.

This version replaces the original version published July 29, 2016.

Introduction

Following the classification of glyphosate announced by IARC (International Agency for Research on Cancer¹) in March 2015, staff in the Office of the Chief Medical Officer of Health (OCMOH) developed an Action Plan in December 2015. The aims of the Action Plan were to:

- Determine how other public health organizations across Canada (and elsewhere) intend to respond to the IARC classification
- Determine the overall contributions of regulatory agencies and other parties (i.e. what they will require or recommend for protective measures given the new information from IARC), and
- Research actual use patterns in New Brunswick (i.e. sectors that use glyphosate, quantities used, application timeframes and application methods) and compare these to human exposure scenarios and human health risk assessments conducted by PMRA (Pest Management Regulatory Agency, Health Canada) to determine if there are any significant differences that might warrant different advice or actions than what is required by the PMRA pesticide label

This report presents the Action Plan's findings for consideration by the Acting Chief Medical Officer of Health to determine if any additional action is required in relation to public health and glyphosate use in New Brunswick.

¹ IARC is an agency of the World Health Organization (WHO) and is headquartered in Lyon, France

Summary of Principal Findings

Responses from Health Agencies to the IARC Classification

- Public Health agencies across Canada and elsewhere are generally in a “wait and see” mode; most are deferring to pesticide regulatory agencies for guidance

Requirements by Regulatory Agencies

- Regulatory agencies are still grappling with glyphosate health risk assessments, as scientific consensus has not been reached
 - PMRA (Health Canada) and the EPA in the United States both began reassessments of glyphosate in 2009/10 as part of routine pesticide licence renewals but these were significantly delayed by rapidly-evolving new information and are still in progress. While initially expected in 2015, completion of these efforts is delayed until at least 2017
 - The European Union completed their scientific assessment (also begun in 2010) but it has been very controversial: several EU member states publicly opposed the findings and so an extension for the re-registration deadline was granted until the end of 2017 to permit a further review by the European Chemicals Agency (ECHA)

Initiatives by Other Parties

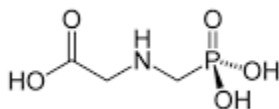
- The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) concluded in a special meeting in May 2016 that glyphosate was unlikely to cause cancer in humans due to expected residue levels on foods grown with the use of glyphosate. However, this risk assessment did not consider any other exposure routes aside from dietary exposures
- The National Collaborating Centre for Environmental Health (NCCEH) is currently developing a synthesis of regulatory information on glyphosate and other pesticides, with consideration of exposure pathways. In addition, CAREX Canada is preparing environmental / occupational exposure estimates for glyphosate. However, it is not yet clear when this information will be available

Use Patterns in New Brunswick

- Total glyphosate use in NB appears to be less intensive than the Canadian average, but
- Glyphosate use patterns in NB are considerably different from elsewhere in the world:
 - Forestry is by far the predominant sector in NB (61% of 2014 glyphosate use)
 - Industrial use is the next most significant sector (27% of total in 2014)
 - Agricultural use is proportionately much lower than elsewhere (90% of worldwide use is in agriculture; NB's proportion was only 11% in 2014)
 - However, the proportion used on genetically-modified herbicide-tolerant crops versus conventional crops in NB is similar to the worldwide rate
- Glyphosate is used in forestry operations in New Brunswick more often than the Canadian average
 - NB ranked second among provinces (after Ontario) in hectares of forest land treated with glyphosate in 2014
 - 28% of all the forest land in Canada treated with glyphosate in 2014 was in NB, but
 - Only 14% of all the forest land in Canada harvested in 2014 (excluding QC, which does not apply forest herbicides) was in NB
- NB requires all industrial and commercial users of pesticides to have a Permit issued by DELG that makes specific restrictions beyond those imposed by PMRA. Enforcement of these conditions can be beneficial in reducing exposures of workers and the public below what is assumed in the PMRA risk assessment
- There is no information available about domestic usage of glyphosate in NB, but provincial rules under the *Pesticides Control Act* that forbid certain domestic class products should ensure that New Brunswickers have lower exposure to glyphosate from the products that are available than the exposures that are assumed in the PMRA risk assessment
- Although glyphosate is used in forestry operations in New Brunswick more often than the Canadian average, OCMOH found no evidence to suggest that this poses a risk to worker safety. A specific case study was examined which indicated that the quantities of glyphosate handled in aerial forest spraying in New Brunswick were less than the maximum quantities assumed in the PMRA risk assessment, and so the PMRA scenario is protective of New Brunswick workers in this industry

Background

Glyphosate (IUPAC name N-(phosphonomethyl)glycine, CAS Registry Number 1071-83-6) is a non-selective herbicide: that is, a chemical that kills almost all plants equally well. It is used for a wide variety of purposes in forestry and agriculture, and for weed control in industrial, commercial and domestic settings.



Chemical Structure of Glyphosate (acid form)

Glyphosate is a synthetic amino acid derivative that is used in herbicide products as either the glyphosate free acid or as one or more of various salts of this compound². Inclusion of other additives such as surfactants leads to a very wide variety of commercial formulations: over 750 different commercial products containing glyphosate are sold in the United States (IARC 2015), and 169 products are registered³ for use in Canada (list available in PMRA 2015, Appendix I). Glyphosate is currently the most widely-used herbicide in Canada (PMRA 2015), the United States and the world (Benbrook 2016).

On March 20, 2015, IARC classified glyphosate as Group 2A, “probably carcinogenic to humans”, a finding that was immediately controversial as previous assessments by other agencies had concluded that glyphosate was most likely not carcinogenic. An overview of the IARC classification rationale is presented in Appendix 1.

It should be noted that the IARC evaluation (IARC 2015) is a hazard classification, not an assessment of the risk posed by the hazard: it indicates the strength of evidence that glyphosate can cause cancer, but the probability of developing a cancer will depend on other factors such as the type and extent of exposures and the strength of the effect of the agent. Thus, a hazard classification needs to be coupled to exposure estimates in order to estimate the health risk posed by a particular chemical.

Health risk assessments such as these are typically undertaken by national regulatory authorities and are used to set restrictions on product use. In Canada, PMRA assesses risks for pesticides, and from these findings specifies requirements for use that must appear on the pesticide label for each registered product. However, PMRA’s risk analysis of the safety of glyphosate (or any pesticide) is based mainly on the assumption that it is used in accordance with these label requirements. It is therefore necessary to investigate how the product is used

² These include the isopropylamine, ethanolamine, mono-ammonium, diammonium, potassium or dimethylamine salts. The trimethylsulfonium (“trimesium”) salt was also used previously but has since been voluntarily discontinued in Canada

³ “Glyphosate is registered for use on the following Use-Site Categories (USC): Forests and Woodlots, Industrial Oil Seed Crops and Fibre Crops, Terrestrial Feed Crops, Terrestrial Food Crops, Industrial and Domestic Vegetation Control Non-food Sites, Ornamentals Outdoors and Turf” (PMRA 2015)

in New Brunswick to ensure that usage here is adequately represented by the PMRA risk assessment's exposure scenarios.

Responses from Health Agencies to the IARC Classification

Provincial and Territorial Public Health Agencies

Chief Medical Officers of Health from each province and territory were sent a questionnaire (see Appendix 2) by email asking what actions, if any, their jurisdictions have taken, or intend on taking in the future, in response to IARC's classification of glyphosate.

Summary of responses received:

- The Chief Public Health Office in Prince Edward Island responded that they had conducted their own review in 2014/15 of the scientific evidence regarding pesticide use and human health (PEI 2015a, b). This review concluded that pesticides used in PEI do not pose a significant public health risk when used according to Health Canada's usage and safety precaution labeling (PMRA). The Chief Public Health Office indicated that they will continue to monitor ongoing research in this area. There is no planned response to IARC's classification at this time
- Nova Scotia is not considering actions at this time to respond to the recent change in the IARC classification for glyphosate, but would reconsider this if PMRA changed their assessment and actions on glyphosate or if the results of the New Brunswick review suggest a change is necessary
- Manitoba, Saskatchewan and British Columbia all indicated that they rely on and would follow PMRA's recommendations
 - In addition, Manitoba noted that they have provincial legislation that bans cosmetic use of pesticides on lawns and the grounds of specified facilities such as schools, child care centres and hospitals. However, pesticides are permitted for use in agriculture, forestry, golf courses and other uses as prescribed by regulation. Manitoba is currently consulting Manitobans on the cosmetic use of pesticides and their experience with this legislation.
- Alberta indicated that they would wait for the final glyphosate re-evaluation from Health Canada before reviewing their position on the human health risks associated with the different uses of glyphosate
- Ontario indicated that they did not have any initial issues or concerns following IARC's classification, but following New Brunswick's inquiry they are now looking more closely at glyphosate use and regulation in their province as well
- The Institut national de santé publique du Québec (INSPQ) is evaluating the IARC's classification and the scientific literature about glyphosate toxicity. At present, Québec does not plan to respond to IARC's classification. It was also noted from published sources (Fortier 2005, NRCAN 2011) that Québec has had a ban on herbicide application on public forest lands since 2001 (this applies to all herbicides, not just glyphosate)

- Nunavut and the Northwest Territories have no significant usage of glyphosate and do not plan to respond to IARC's classification
- Newfoundland and Labrador, and Yukon did not respond

Public Health Agencies Outside of Canada

Public Health agencies in the two nearby states that were successfully contacted (Maine and Vermont) referred OCMOH staff to their respective pesticide regulators (Board of Pesticides Control, Maine Department of Agriculture, Conservation and Forestry; Vermont Agency of Agriculture). Neither state currently has any plans to review glyphosate use following the IARC classification, but Vermont indicated that they are waiting for guidance from EPA's ongoing review. In addition, Vermont noted that while herbicides are permitted for industrial and agricultural uses, they have had a ban on all herbicide application in forestry since 1997.

Requirements by Regulatory Agencies

Pest Management Regulatory Agency (PMRA), Health Canada

In 2010, in collaboration with the United States Environmental Protection Agency, Health Canada's Pest Management Regulatory Agency (PMRA) published a re-evaluation work plan for glyphosate⁴. Using data from registrants, published scientific reports, information from other regulatory agencies and other relevant information, the re-evaluation considered "the potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment" (PMRA 2015). Aminomethyl phosphonic acid (AMPA), which is the major metabolite of glyphosate, and Polyethoxylated Tallow Amines (POEA), a family of compounds used as surfactants in many glyphosate products, were also included in the re-evaluation.

On April 13, 2015, Health Canada released its Proposed Re-evaluation Decision on Glyphosate (PMRA 2015). The major health-related findings stated in the report were:

- *"Products containing glyphosate do not present unacceptable risks to human health or the environment when used according to the proposed label directions"*
- *"Products containing glyphosate acid are unlikely to affect your health when used according to label directions"*
- *"Dietary risks from food and water are not of concern"*
- *"Non-occupational risks are not of concern when used according to label directions"*
- *"Non-occupational risks from bystander dermal exposure are not of concern"*
- *"Occupational risks to handlers are not of concern when used according to label directions"*
- *"Post application (occupational) risks are not of concern for all uses"*
- *"No human health risks of concern were identified for POEA's, provided end-use products contain no more than 20% POEA by weight. All registered glyphosate products in Canada meet this limit"*

Continued registration of all products containing glyphosate for sale and use in Canada was proposed, but the following additional label requirements (directions that are to be followed by law) to minimize risk to human health were also put forward as a condition of the continued registration:

- *"To protect workers entering treated sites, a restricted entry interval of 12 hours is proposed for agricultural uses⁵"*
- *"To protect bystanders, a statement indicating to apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal is required"*

⁴ "Re-evaluation Work Plan for Glyphosate, REV2010-02", available on request from [http://www.hc-sc.gc.ca/contact/order-pub-commande-eng.php?title=PMRA \(REV2010-02\) Re-evaluation Work Plan for Glyphosate](http://www.hc-sc.gc.ca/contact/order-pub-commande-eng.php?title=PMRA%20(REV2010-02)%20Re-evaluation%20Work%20Plan%20for%20Glyphosate)

⁵ A restricted entry interval was already required for other uses such as forestry

Also included in the report was a statement which directly addressed IARC's classification for glyphosate as "probably carcinogenic to humans":

"It is important to note that a hazard classification is not a health risk assessment. The level of human exposure, which determines the actual risk, was not taken into account by WHO (IARC). Pesticides are registered for use in Canada only if the level of exposure to Canadians does not cause any harmful effects, including cancer." (PMRA 2015)

Although PMRA published the draft Proposed Re-evaluation Decision for a 60-day public comment period in April 2015, there have been no subsequent follow-up documents posted on the website since then⁶. As a result, OCMOH staff inquired to PMRA directly re the status and received the following reply⁷ :

"In response to this consultation document, the PMRA received a large number of comments from a variety of stakeholders. The PMRA is now considering all the comments received before making a final regulatory decision. The PMRA will then publish a Re-evaluation Decision that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments. The final decision document is anticipated to be no later than March 2017, as indicated in the current 5-year re-evaluation workplan (REV2016-07, <http://www.hc-sc.gc.ca/cps-spc/pubs/pest/decisions/rev2016-07/index-eng.php>)"

⁶ As of May 27, 2016 based on documents available at (PMRA 2015)

⁷ Email from PMRA to OCMOH, May 27, 2016

United States Environmental Protection Agency (EPA)

EPA initiated a work plan for the re-evaluation of glyphosate in 2009 (USEPA 2009). The last re-registration decision with a full evaluation was done in 1993, and a Tolerance Reassessment and Risk Management Decision update was completed in 1997. There have also been a few other related but less significant regulatory documents published in the interim (all available from ref. USEPA, undated).

The EPA 2009 work plan was coordinated with PMRA in Canada, and according to its original published timeline was supposed to have produced a draft Registration Review Decision for public comment by July – September 2014, and subsequently to be finalized in 2015 (USEPA 2009).

Although PMRA published a draft Proposed Re-evaluation Decision for public comment in Canada in April 2015 (PMRA 2015), the EPA counterpart to this document has not been published yet⁸. Furthermore, EPA's Pesticide Reevaluation Registration Review Schedules⁹ do not indicate a target date for glyphosate for any of: Draft Risk Assessments, Proposed Interim Decisions, Interim Decisions or Decisions that are currently scheduled up until July – September 2016. As a result, OCMOH staff inquired to EPA directly re the status and received the following reply¹⁰:

"The registration review schedule page you mentioned only lists anticipated actions for "FY16," which means the 2016 fiscal year ending at the end of September. EPA opened the registration review case for glyphosate in 2009, as indicated in the glyphosate regulatory docket [this is ref. USEPA, undated]. The review is consistent with the requirements of federal pesticide law and was schedule [sic] to be completed in 2015. But finalizing the review was delayed because new data was presented that the Agency wanted to include in this review rather than waiting for the next cycle. The Agency is taking our analysis of the new data for special peer review, and we anticipate completing the entire review by the end of the 2016 calendar year."

It should also be noted that an "EPA Desk Statement" dated April 1, 2015 has been much cited by several parties in debates surrounding glyphosate, beginning shortly after the IARC announcement last year. This document could not be found on EPA's website or elsewhere on the Internet, but a copy was forwarded to OCMOH via correspondence with a US State agency¹¹ and a portion of it is quoted below. The Desk Statement directly rebutted IARC's findings by citing other previous hazard assessments, but also stated that EPA would release a preliminary human health risk assessment for glyphosate "in a few months" that would address the IARC report in detail. However, this was stated 16 months ago and this document has not yet been released, but it is still in progress as noted by OCMOH's recent correspondence with EPA (release now expected by the end of calendar 2016).

⁸ As of May 27, 2016 based on documents available at (USEPA, undated) the most recent of which was published in 2012

⁹ <https://www.epa.gov/pesticide-reevaluation/registration-review-schedules> accessed May 27, 2016

¹⁰ Email from EPA Pesticide Program Webmail Support to OCMOH, May 27, 2016

¹¹ Email from Vermont Agency of Agriculture to OCMOH, May 27, 2016

April 1, 2015 “EPA Desk Statement” (excerpt):

In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible cancer and non-cancer effects of glyphosate. Our review concluded that this body of research does not provide evidence to show that glyphosate causes cancer, and it does not warrant any change in EPA’s cancer classification¹² for glyphosate. This is the same conclusion reached in 2004 by the United Nations’ Food and Agriculture Organization and affirmed this year by Germany’s pesticide regulatory officials. In a few months, EPA will be releasing for public comment our preliminary human health risk assessment for glyphosate as part of our program to reevaluate all pesticides periodically. EPA is aware of the recent International Agency for Research on Cancer (IARC) report and will address it in detail in the preliminary risk assessment. Additional information regarding glyphosate and EPA’s ongoing registration review can be found at: http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:0::NO:1,3,31,7,12,25:P3_XC_HEMICAL_ID:2477 [this is ref. USEPA, undated]

No information is available yet as to whether EPA is considering revising this position, so determining this will have to wait until release of the much-delayed preliminary risk assessment, now expected to be finished by the end of calendar 2016.

¹² The current EPA cancer classification for glyphosate is “Group E--Evidence of Non-carcinogenicity for Humans” (NPIC 2015)

European Union (EU)

Responsibility for the approval of pesticide active ingredients in the EU rests with the European Commission, which is the executive body of the EU government. Approval by the Commission is granted only after following a defined assessment procedure leading to a vote of the Standing Committee for Food Chain and Animal Health, which includes representatives of EU member states (EU Commission, undated).

The current license for glyphosate use in the EU was set to expire June 30, 2016. In 2010, the European Commission began a regularly scheduled re-evaluation of glyphosate by appointing Germany to be the Rapporteur Member State (RMS) that would collect available information on this substance from registrants and the literature, and prepare a draft scientific assessment for the license renewal process. Germany assigned this task to its Federal Institute for Risk Assessment (BfR, *Bundesinstitut für Risikobewertung*).

BfR completed the initial draft of its report in December 2013 and issued revised reports in February 2015 and again in April 2015 (which was coincidentally shortly after the IARC announcement). Because of the timing, their review did not include any comment on the full IARC monograph on glyphosate, which was not released until July 2015, but they recommended strongly that the EU Commission should carry out a detailed review of it as part of the pesticide registration renewal approval process (BfR 2015; BfR, undated).

The BfR's findings were submitted to the European Food Safety Authority (EFSA), which oversees the safety assessments of all pesticides seeking approval or approved for use in the EU. The EU Commission also mandated EFSA to consider the findings by IARC regarding the potential carcinogenicity of glyphosate as BfR had recommended. EFSA prepared a human health risk assessment based on BfR's findings, considered the IARC monograph as requested, and undertook consultations with member states, experts and the public, and released their conclusions in November 2015 (EFSA 2015a, b).

Amongst other conclusions¹³, EFSA's report stated a directly conflicting opinion to that of IARC's regarding the carcinogenicity of glyphosate:

"...glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation)." (EFSA 2015a)

This conclusion in particular has proved to be highly controversial, and was publicly opposed by way of an open letter from 96 academic and government scientists to the EU Commissioner for Health and Food Safety (The Guardian 2016a, Portier 2016). In the letter, the scientists state that:

¹³ These included an updated toxicological profile with an acute reference dose (ARfD) determined for the first time, an acceptable operator exposure level (AOEL) and an acceptable daily intake (ADI) for consumers (EFSA 2015c); a statement that glyphosate "is not... proposed to be classified as ... toxic for reproduction"; and the identification of many data gaps including a lack of data on endocrine disruption, a lack of toxicological data on 2 metabolites that are relevant to genetically modified plant varieties imported into the EU, a lack of mammalian toxicology on all but 2 possible impurities in technical grade glyphosate, and others (EFSA 2015a)

“The EFSA decision, based upon the Renewal Assessment Report provided by the German Federal Institute for Risk Assessment (BfR), runs counter to the finding earlier this year by the International Agency for Research on Cancer (IARC)... We reviewed these two differing decisions on the human carcinogenicity of glyphosate and conclude that the IARC WG¹⁴ decision is by far the more credible”

EFSA subsequently published a rebuttal (EFSA 2016) but the disagreement is still unresolved, and the controversy is not just about whether glyphosate is carcinogenic or not. For example, a “statement of concern” by a group of academics regarding increasing glyphosate use and the adequacy (or not) of toxicological studies to date specifically cited the BfR risk assessment relied upon by EFSA as recommending a reference dose (which would be used in setting maximum residue limits on foods and acceptable daily intakes) that they considered to be far too high (Myers 2016).

This public disagreement has subsequently contributed to a possible impasse in the re-approval of glyphosate for use in the EU. The EU Commission Standing Committee is divided over the question of re-approving glyphosate use in the EU, which has been proposed to be valid for the next 15 years (the standard re-approval period). France, the Netherlands, Sweden and Italy have all publicly opposed this, and Germany is proposing to abstain from a vote, reportedly due to a disagreement between its own Environment and Agriculture ministries. The issue of re-approval of glyphosate has been on the Standing Committee’s agenda three times (in March, May and June 2016) and despite proposals to renew the license for a shorter time period or to exclude certain products (such as those containing tallow amines) a vote has been postponed each time, apparently because of fears that it would fail based on the current division in the committee (The Guardian 2016b,c,d; Reuters 2016a). This impasse could have led to glyphosate products being in a “legal limbo” in Europe when the current license expired on June 30, 2016, but the European Commission avoided this by extending the license for a limited period of time (end of 2017 at the latest) in order to permit completion of a pending review by the European Chemicals Agency (ECHA) (Reuters 2016b; EU Commission 2016).

Furthermore, the EU Parliament (which has no authority over the re-registration process) voted in favour of a resolution in April 2016 that “the EU Commission should renew its marketing approval for just 7 years, instead of 15, and for professional uses only” (EU Parliament 2016, EU Parliament News 2016). This resolution is non-binding on the EU Commission but it has been interpreted by some as being a reflection of public opposition to glyphosate, as MEPs (Members of the European Parliament) are elected by the public.

In addition, the EU Parliament resolution called for a reassessment of glyphosate after the pending review by ECHA, including an assessment of endocrine disruption potential; public disclosure of all of the unpublished corporate scientific studies submitted by registrants to EFSA; a ban on the practice of “green burndown” (desiccation of crops prior to harvest); and bans on glyphosate use in public parks and playgrounds (EU Parliament News 2016).

¹⁴ WG = working group

Initiatives by Other Parties

Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

JMPR is a committee of international scientific experts that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It meets annually to discuss and make recommendations on issues related to pesticides, including analytical aspects, reviews of toxicological data, estimates of maximum residue levels (MRLs) that could be permitted in foods, and estimating acceptable daily intakes (ADIs) of pesticides by humans (FAO, undated; WHO, undated).

It should be noted that the WHO representatives on JMPR are separate from IARC (which is also a WHO agency). The WHO representatives are from its Core Assessment Group on Pesticide Residues, while the FAO representatives are from its Panel of Experts on Pesticide Residues in Food and the Environment.

JMPR held a special meeting on May 9-13, 2016 to consider the glyphosate issue, as well as two other pesticides that were also part of the same IARC review. The findings were published in a report (JMPR 2016a) and a summary report (JMPR 2016b). In addition, a Frequently Asked Questions format was used to put the findings of the report in context (JMPR 2016c).

JMPR's most significant finding was that glyphosate was "*unlikely to cause cancer in people via dietary exposure*". Although media reports (e.g., The Guardian 2016e) generally considered this to be a contradiction of IARC's findings, this not the case: indeed, JMPR has stated directly that its findings and those of IARC are not contradictory (JMPR 2016c, Question 9). The distinction lies in the context: while JMPR critiqued the suitability of the studies relied upon by IARC and discounted some of them, they were unable to do so for others including some studies of cancers in mice and genotoxicity in vitro. However, JMPR considered the equivalent doses in these studies to be far higher than what would be expected from human dietary exposures, and gave less weight to all studies that were not based on oral exposures of mammals, and concluded as a result that human carcinogenicity from foodborne residues of glyphosate was unlikely.

This context is important and should be noted in any risk communications, as the idea that JMPR's findings contradict those of IARC seems to be firmly rooted in media reports and has been used by some commentators to discredit IARC, but the comparison is factually inaccurate. While EFSA (EFSA 2015a) directly disputed IARC's hazard assessment, JMPR did not (apart from many details regarding which studies it considered reliable or not, or relevant irrespective of reliability).

Additionally, it should be noted that JMPR considered only the oral exposure route and only exposures resulting from foods bearing residual pesticide at expected levels. As a result, their findings are based on a partial risk assessment that did not consider all possible human exposures, which is less complete than those conducted or in progress by EFSA, EPA and PMRA. Nevertheless, JMPR's conclusion that glyphosate residues on food are unlikely to constitute a cancer risk is an important piece of the puzzle.

National Collaborating Centre for Environmental Health (NCCEH) and CAREX Canada

NCCEH is one of six specialized National Collaborating Centres for Public Health¹⁵ across Canada that are mandated to “*identify knowledge gaps, foster networks and provide the public health system with an array of evidence-based resources, multi-media products, and knowledge translation services*”. NCCEH is hosted by the Provincial Health Services Authority at the BC Centre for Disease Control in Vancouver, BC. OCMOH staff had two teleconferences with NCCEH staff during the course of this Action Plan to determine what activities they had planned or ongoing in response to the IARC assessment of glyphosate.

NCCEH is currently working on synthesizing relevant information and preparing knowledge translation products related to glyphosate and other pesticides, with consideration of exposure pathways. The NCCEH is working with CAREX Canada and with the Canadian Environmental Law Association to conduct an environment scan on the regulations that govern glyphosate and other pesticides and compare these regulations across jurisdictions in Canada.

CAREX¹⁶ is Canada's only national carcinogen surveillance program, which estimates the number of Canadians exposed to substances associated with cancer in workplace and community environments. Funded by the Canadian Partnership Against Cancer, CAREX generates estimates of exposures to 80 different agents that Canadians are exposed to at home and work. Given the recent IARC classification and the large exposure potential due to its widespread use, CAREX is currently working to include Canadian environmental and occupational exposure estimates for glyphosate in addition to the substance profile already prepared (CAREX 2016).

Once it becomes available, this information from NCCEH and CAREX will be very valuable for risk communications and public health messaging because of its Canadian context, but it is not yet clear when it will be available. OCMOH staff will continue to engage with both NCCEH and CAREX on this file, however, and future advice to the ACMOH may be made based on their findings.

¹⁵ <http://www.nccph.ca/6/About-us.ccnsp>

¹⁶ <http://www.carexcanada.ca/en>

Use Patterns in New Brunswick

Amounts Used by Sector

Data were obtained from the Department of Environment and Local Government (DELG 2016).

Approximate Quantities of Glyphosate Products applied in NB by Sector in 2014

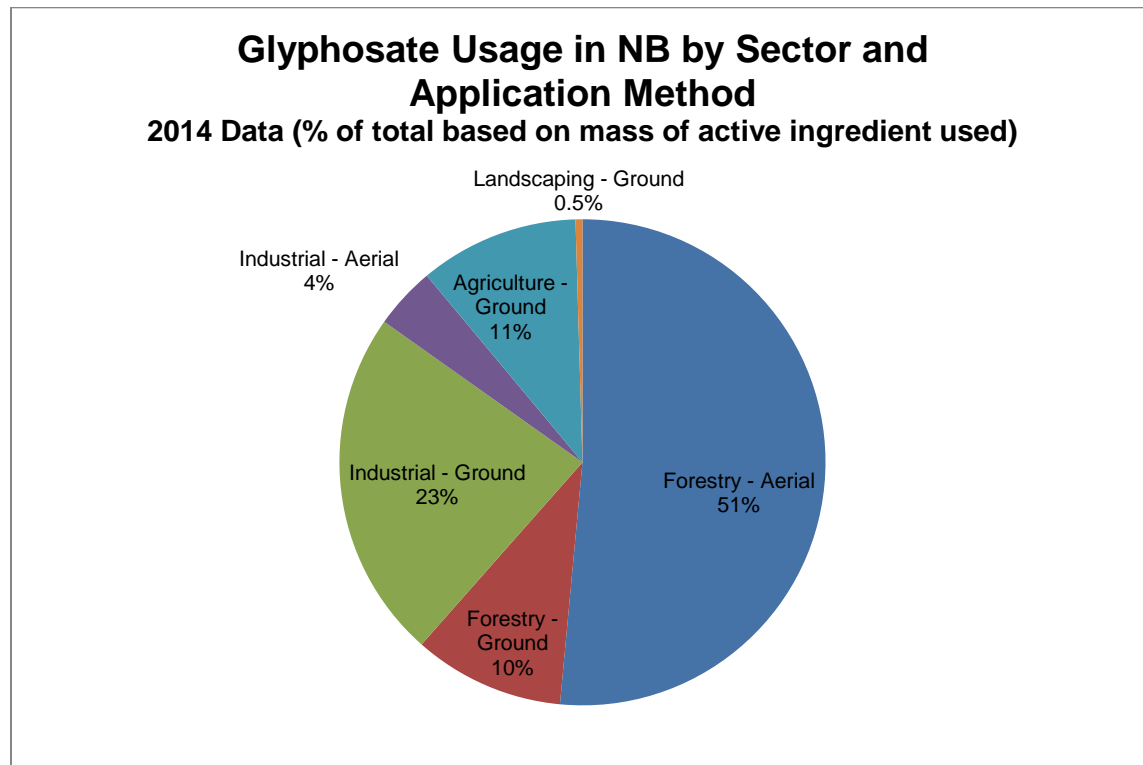
Sector - Application Method	Volume (L)*	Approx. kg a.i.**	Percent of Total (by Volume)	Percent of Total (by Mass of a.i.)***
Forestry - Aerial	90,880	32,703	60%	51%
Forestry - Ground	13,178	6,378	8.7%	10%
Industrial - Ground	27,567	14,801	18%	23%
Industrial - Aerial	4,847	2,617	3.2%	4.1%
Agriculture - Ground	14,389	6,739	9.5%	11%
Landscaping - Ground ****	606	291	0.4%	0.5%
Domestic (retail sales)	Unknown	Unknown	Unknown	Unknown
Total	151,467	63,529	100%	100%

* Litres of concentrated products (typical glyphosate concentration 356 to 540 g/L) before dilution

** Values are estimated (DELG 2016). Kg a.i. = kilograms of active ingredient

*** Note that percentages of total have historically varied from year to year, but the 2014 data are the most recent and highest quality data available

**** Professional use only



New Brunswick Use Patterns Compared to Other Jurisdictions

The distribution of glyphosate use in New Brunswick (see Table and Chart above) is heavily weighted toward use in Forestry (61% of 2014 total by mass of a.i.), followed by Industrial uses (27%) and then Agriculture (11%). Landscaping usage (0.5%) is very minor in comparison to other uses, but note that this figure includes only glyphosate applied by professional applicators, as the amounts used for Domestic application (i.e. from products available directly to homeowners at retail stores) cannot be estimated because DELG tracks only sales of concentrates to licensed distributors and applicators. The principal glyphosate-containing concentrated products used in New Brunswick are listed in Appendix 3.

Although this use pattern varies somewhat from year to year (sometimes significantly)¹⁷ it is always considerably different from other jurisdictions in that forestry use of glyphosate in NB amounts to a much larger proportion, and agricultural use of glyphosate in NB amounts to a far smaller proportion of total usage than elsewhere.

For example, glyphosate use worldwide is dominated by the agricultural sector, in large part because of its widespread and rapidly increasing use in farming of genetically-modified herbicide-tolerant crops. In 2014, 90% of the more than 825 million kilograms of glyphosate applied globally was used in agriculture, as was over 90% of the more than 125 million kilograms of glyphosate applied in the United States (Benbrook 2016).

Precise usage figures by sector in Canada were not readily available, but agriculture has been noted as the primary use of the more than 25 million kilograms of glyphosate sold annually in Canada (CAREX 2016). Again, this has largely been driven by farming of genetically-modified herbicide-tolerant crops, which include canola, soybean, field corn, sweet corn, sugar beet and others (PMRA 2015), although conventional non-genetically-modified crops also account for nearly half of total glyphosate used in agriculture worldwide (Benbrook 2016).

Note that the reported total kilograms used in New Brunswick are less than 0.3% of the Canada-wide usage. Since New Brunswick constitutes 2.1% of the Canadian population¹⁸ and 0.7% of the land area¹⁹, it appears that glyphosate use is less intensive in NB than in other parts of Canada, on average.

¹⁷ Personal communication from DELG to OCMOH, May 20, 2016

¹⁸ Calculated from data as of July 1, 2015. Statistics Canada, CANSIM, table [051-0001](http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/demo02a-eng.htm), last modified: 2015-09-29, <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/demo02a-eng.htm>

¹⁹ Natural Resources Canada, GeoAccess Division. Last modified: 2005-02-01 <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/phys01-eng.htm>

Forestry Uses of Glyphosate in New Brunswick

As noted above, the Forestry sector is by far the predominant user of glyphosate in New Brunswick. Indeed, New Brunswick, despite having only 0.7% of Canada's land area, ranked second among Canadian provinces (after Ontario) for hectares of forest that were treated with glyphosate in 2014 (NFD 2016):

Application of Forest Herbicides, 2014 (reproduced from NFD 2016)														
(Hectares)														
Product	NL	PE	NS	NB	QC	ON	MB	SK	AB	BC	YT	NT	NU	CA
2,4-D	..	-	-	-	-	..	-	-	-	..	-
Glyphosate	135	91 e	3 464	28 624 e	-	33 394 e	1 911 e	-	17 386 p	15 724 e	-	100 729 e
Hexazinone	..	-	-	-	-	..	-	-	-	..	-
Other herbicides	..	-	-	-	-	402 e	-	-	3 627 p	1 355 e	-	5 384 e
Total	135	91 e	3 464	28 624 e	-	33 796 e	1 911 e	-	21 013 p	17 079 e	-	106 113 e

Source: National Forestry Database, *Updated: 2016-02-12*

... Figures not appropriate or not applicable p Preliminary figures
 .. Figures not available r Revised figures
 -- Amount too small to be expressed e Estimated by provincial or territorial forestry agency
 - Nil or zero

In addition, a data export from the National Forestry Database (NFD 2016)²⁰ was used to determine the total forest land area harvested in 2014 in all provinces and territories, and in Canada.

²⁰ "Create Your Own Report" Query parameters: Reporting Agencies = all provinces and territories, and Canada; Reporting Items = Silviculture – Area Harvested – Total; Reporting Period = 2014

2014 Data	Total Area Harvested (ha)	Area treated with Glyphosate (ha)	% of total area
NL	7 037	135	2%
PE	2 760 e	91	3%
NS	32 187 e	3464	11%
NB	72 085	28624	40%
QC	205 859 e	-	0%
ON	117 230	33394	28%
MB	10 686 e	1911	18%
SK	17 701 e	-	0%
AB	83 786 p	17386	21%
BC	167 238	15724	9%
YT	300 e	-	0%
NT	190 e	...	0%
NU	0%
CA	717 059 e	100729	14%
CA - QC	511200	100729	20%

Based on these data and those in the table above, it can be calculated that:

- Approximately 28% of the forest land area in Canada treated with glyphosate in 2014 was in New Brunswick
- 10% of the total forest land area in Canada (14% excluding Québec)²¹ harvested in 2014 was in New Brunswick
- The forest area treated with glyphosate in New Brunswick in 2014 amounted to 40% of the total forest land area harvested in the province that year²²
- The forest area treated with glyphosate in Canada in 2014 amounted to 14% of the total forest land area harvested in the country (20% excluding QC) that year

Since New Brunswick accounted for 28% of Canada's forest land area treated with glyphosate in 2014 but only 14% of the total land area harvested (excluding Québec as noted in Footnote 21), and since the forest area in Canada treated with glyphosate in 2014 amounted to 14% (20% excluding Québec) of the total harvested area, compared to 40% in NB (which was the highest among all provinces and territories), it can be concluded that glyphosate appears to be used in forestry operations in New Brunswick more often than the Canadian average²³.

Nevertheless, only about 1% of New Brunswick's forest is harvested each year (ForestInfo.ca, undated), and of these areas, approximately one-third are treated with glyphosate. An online interactive GIS-linked map layer (GeoNB, undated) is available that shows the exact locations and boundaries of proposed spray areas on Crown lands, and a static map of glyphosate spray areas on Crown and Private lands in 2015 is also available (JDI, 2015).

²¹ Québec was excluded as this province does not permit the general use of herbicides in forestry (therefore in this calculation NB is compared only to those provinces that do permit the use of herbicides in forestry)

²² An independent estimate of the typical fraction that might be treated (33%) is stated online (ForestInfo.ca, undated)

²³ Since these are preliminary findings based on OCMOH's own calculations, these observations should be peer reviewed and studied in more detail over a longer time frame (e.g. by Canadian Forest Service scientists) before being considered as definitive

Timing and Application Methods in Forestry

Glyphosate is commonly used in forestry operations in Canada and elsewhere as part of efforts to regenerate commercial forests following tree harvesting. This is because there are many “pioneer” plant species (such as grasses, raspberry, pin cherry and poplar) which are well-adapted to open / recently-cut areas and thus can out-compete the tree seedlings introduced by replanting of these areas.

Although there are other reforestation options such as planned natural regeneration, manual or mechanical site preparation, controlled fire and others that are used in many cases, herbicide use is often the most cost effective, efficient and reliable method to regenerate conifer plantations, and may reduce certain worker health risks such as physical injury from equipment. Furthermore, such herbicide use may in fact be necessary in order to achieve the wood supply regrowth rates required to meet harvest sustainability targets in conifer-dominated stands (NRCAN 2011).

The application of glyphosate to forest lands is typically used as part of one of two strategies: chemical site preparation (knockdown of existing vegetation prior to planting) or after coniferous tree seedlings are planted and established for 2 to 5 years in a process called “conifer release”²⁴. Each regeneration area is typically sprayed only once (at most twice) in a 40 to 80 year rotation period from planting to harvest (NRCAN 2011; ForestInfo.ca, undated). In New Brunswick the application of glyphosate to forest lands typically occurs in late summer to early fall (mid-August to mid-September).

Most of the glyphosate used in New Brunswick forestry is applied by aerial spraying (84% based on data in DELG 2016); in Canada over 88% of the glyphosate applied to forests in the last decade was by aerial application from fixed- or rotary-wing aircraft (ForestInfo.ca, undated). Ground application methods include tractor mounted and backpack sprayers (ForestInfo.ca, undated) as well as potentially other methods also registered by PMRA for Use-Site Category 4, Forest and Woodlands (PMRA 2015, Appendix IIa) which include boom or boomless application, mist blowers, roller, wick or injection systems, and cut stump application.

²⁴ Since glyphosate kills all plants, application after planting the new trees seems counterintuitive, but conifer seedlings are selectively preserved because of the timing of application: in late summer / early fall other vegetation is typically growing more actively (which results in a greater toxic effect on the plant) than the conifer seedlings are

Industrial Uses of Glyphosate in New Brunswick

Information was not readily available on industrial uses of glyphosate in New Brunswick except for spraying along NB Power electrical transmission line rights-of way and around electrical grid facilities. However, possible uses in this category include weed control at industrial sites such as railroads, pipelines, highways, telephone and power rights-of-way, petroleum tank farms, pumping installations, roadsides, storage areas, lumberyards, fence rows, and industrial plant sites (PMRA 2015).

Since glyphosate is only effective on actively growing plants after leaves have emerged, the main application time frame is expected to be from late spring until early fall (approximately May to October). Depending on the setting, spot application or broadcast spraying could be used, but all of these activities for most industrial uses are expected to have the objective of knocking down all vegetation rather than more selective approaches such as those used in managing crops or forest plantations. Electrical transmission lines are an exception in this respect, as the objective is not to eliminate all vegetation but to keep a low-growing, stable plant community that will not interfere with the lines but will hinder the growth of taller non-compatible plants.

NB Power has published information regarding its vegetation management program along transmission lines and at facilities (NB Power, undated; NB Power 2015). Their Integrated Vegetation Management Plan (NB Power 2015) notes that glyphosate-containing herbicide products can be used in all of the herbicide application methods outlined in the plan, including backpack sprayers, aerial (helicopter), truck or machine-mounted sprayers, swabs, spot applicators, injectors, and attachments for brush saws and bush hog mowing machines that apply herbicide to stumps while cutting.

NB Power typically manages vegetation along rural power line rights-of-way every three to four years, using both cutting crews and herbicide application on approximately 50% of the area. A number of other herbicides besides glyphosate are also used for particular applications. All applications are subject to the conditions in DELG Permits such as setbacks and notifications prior to spraying, although NB Power has also voluntarily committed to a much larger setback from dwellings (150 metres) than that specified in their Permit (15 metres; NB Power, undated).

With respect to direct comparisons of New Brunswick's industrial usage to elsewhere, this could not be achieved with certainty as no comparable data was identified from other jurisdictions.

Agricultural Uses of Glyphosate in New Brunswick

Although only a relatively small percentage of glyphosate use in NB is in the agricultural sector, this usage was explored in more detail to better understand how and when it is applied.

Information provided by the New Brunswick Department of Agriculture, Aquaculture and Fisheries (DAAF 2016) indicates that glyphosate is used in a broad variety of agricultural activities, including:

- During initial land clearing to control undesirable woody plants
- Before seeding crops to control emerged weeds
- As a selective weed control treatment within Roundup Ready® crops, such as field corn, soybean, sugar beet and canola (Roundup Ready® crops are one type of many genetically-modified herbicide-tolerant crops approved for use)
- As a wiper or roller treatment to control weeds growing above fruit and vegetable crops
- As a non-selective spot treatment to control aggressive and potentially invasive weeds such as giant hogweed and Japanese knotweed
- To stop growth of crops to facilitate crop harvest or stand renewal
- As an injection or a cut stump treatment for control of woody tree species

The most common crops grown in New Brunswick are listed in Appendix 4. In approximate decreasing order from most hectares planted to the least, the uses of glyphosate on particular crops in NB are:

Forage, Grains and Potatoes

Glyphosate is generally applied by boom sprayer. The amount used is fairly low and is applied generally pre-planting in early May/June. The forage industry may also have an application at the end of the season.

Blueberries

Glyphosate is generally applied by wiping treatment with some limited use of “back-pack” application. These are “over-top” and spot treatments which occur in July/August. The amount used is low. Also, Glyphosate may be used in the late fall on newly cleared land and the application amount in this case would be somewhat higher.

Corn and Soybeans

These crops would make up the largest portion of Roundup Ready® crops. DAAF estimates that about 10,000 hectares in New Brunswick are planted with genetically-modified herbicide-tolerant crops, and that these account for approximately 60% of the total amount of glyphosate used in agriculture in NB (DAAF 2016). This fraction is consistent with one estimate that 56% of total worldwide agricultural glyphosate use in 2012 was applied to genetically-modified crops, with the remainder used in farming of conventional crops (Benbrook 2016).

Cranberries

Growers generally use the “wiping” treatment.

Apples

Glyphosate is applied with directed spray around trees early in the season, although most producers are moving away from glyphosate use due to damage to the trees.

Strawberries

Glyphosate would be applied using spot treatment.

Controls on Glyphosate Exposure in New Brunswick

Pesticides in Canada are regulated both provincially and federally.

Provincial Level

The Department of Environment and Local Government (DELG) is responsible for the management of pesticides and their application in New Brunswick. Any pesticide used in New Brunswick must be registered with the federal PMRA, which includes specific restrictions on use (known as the “label requirements”), but the *Pesticides Control Act* (RSNB 2011) and *New Brunswick Regulation 96-126* provide additional requirements aimed at increasing the safety of pesticide use.

These additional New Brunswick requirements fall into two principal categories: Commercial Grade Products (used in Forestry, Industrial, Agricultural and Landscaping sectors), and Domestic Class Products (available directly to homeowners at retail stores).

1. Commercial Grade Products

The proposed updates to PMRA label requirements for commercial and agricultural class products containing glyphosate (PMRA 2015) specify buffer zones to protect non-target plant species in freshwater, estuarine/marine and terrestrial environments, but these setback distances are not specifically based on human health protection.

The proposed label statements (PMRA 2015) also state *“Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.”*

In the New Brunswick context, all commercial or industrial uses of pesticides must have a Permit from DELG issued under the authority of the *Pesticides Control Act* and *Regulation* that contains additional conditions²⁵ that must be met in addition to all PMRA label requirements.

Two current Permit documents²⁶ issued by DELG (DELG 2016) were reviewed. Although specific conditions can potentially be different between different Permits, the contents of these two examples were deemed to be representative of the Forestry and Industrial use sectors. The following conditions were noted that could have a bearing on health protection by potentially reducing human exposure to pesticides further than what the PMRA label requires:

²⁵ It was also noted that while DELG responds to complaints and does some routine audits, they are currently updating their Permit compliance process to specify a percentage of Permits to audit, frequency based on past compliance performance, etc., (personal communication from DELG to OCMOH, March 18, 2016).

²⁶ The specific documents reviewed were *New Brunswick Aerial Pesticide Permit Number 5605 (issued 2016/02/22)* and *New Brunswick Ground Industrial Pesticide Permit Number 2016 5318*

Permit Condition	Forestry (aerial) example	Industrial (ground) example
Pesticide Applicator Certificates are required for designated personnel (certifies that the individual has appropriate education and training)	Required for application of pesticides, guidance of spray aircraft, ground forestry supervision of pesticides, mixing or loading of pesticides	Required for application, mixing or loading of pesticides
Only Authorized Products (specifically listed in the Permit) may be applied	Vision Forza Vision Max	Vision Max + other (non-glyphosate) pesticides
Only Authorized Treatment Sites (specifically listed in the Permit) may be sprayed	Land parcels identified by PID (Property ID) listed in the Permit	Power transmission lines identified by Number and start/end locations listed in the Permit
Personal Protective Equipment	Specifications in Permit for all mixing/loading personnel	Specifications in Permit for all mixing/loading personnel and all applicators
Setbacks / Buffers	Access to treatment area must be controlled during application No application closer than: <ul style="list-style-type: none"> • 155 metres from occupied habitation • 50 metres from property boundaries if drift can occur to adjacent properties • 65 metres from surface water • 3.2 kilometres upstream of an intake for a municipal surface drinking water supply No mixing or loading within 30 metres from surface water	No application closer than: <ul style="list-style-type: none"> • 15 metres from occupied habitation • 15 metres from property boundaries if drift can occur to adjacent properties • 30 metres from the nearest edge of a public highway right-of-way or crossing (with some exceptions) • 15 metres from surface water (except when using wipe applicators) • 30 metres from the banks of a watercourse within 1 kilometre upstream of the intake for a public water supply
Wind Speed Limits	No application if > 16 km/h	No application if > 10 km/h
Signage (“ATTENTION: Pesticide Application” + required info about product)	Post prior to, during and after application at all ordinary access points to treatment sites	Post prior to, during and after application at all ordinary access points to treatment sites
Advance Notifications	Fire Department, Dept of Public Safety, general public notice 14 days prior, residents within 500 metres 24 hours prior (with specified info), municipalities if within their boundaries	Fire Department, Dept of Public Safety, general public notice 14 days prior (with specified info), municipalities if within their boundaries
Storage and Disposal	Requirements as specified in Permit; additional requirements for Transport also	Requirements as specified in Permit

2. Domestic Class Products

In 2009, New Brunswick introduced a policy (DELG 2009a) under the *Pesticides Control Act* that effectively banned certain types of pesticide products intended for Domestic use that had previously been available through general retail sales. Although the rules are not specific to glyphosate, they are also applicable since they apply to all Domestic class products. The banned products included:

- Combination Products (e.g. fertilizer with pesticides included)
- Hose-End Products
- Concentrates and Products Requiring Preparation
- Granular Spreadable Products
- Pesticide Products Containing the Pesticide Ingredient 2,4-Dichlorophenoxyacetic Acid (2,4-D)
 - This last ban also extended to Commercial Grade Products (DELG 2009b) with the exception of still being permitted only for golf course maintenance by IPM (Integrated Pest Management) accredited organizations

These restrictions can have a significant effect in reducing exposures of non-professional pesticide users to Domestic Class Products: for example, the ban on concentrates means that only ready-to-use products can be sold, thereby effectively eliminating exposures from mixing and loading of chemicals.

Federal Level

Health Canada's National Pesticide Compliance Program is responsible for promoting, monitoring and enforcing compliance with the federal *Pest Control Products Act* and its Regulations. This is achieved through collaboration between two Health Canada agencies: PMRA and the Regions and Programs Bureau (RAPB). The compliance program focuses on three main areas:

- **Active prevention** through education and outreach activities
- **Targeted oversight** which monitors compliance with the *Pest Control Products Act* through formal inspections, interviews and sampling
- **Rapid response** to situations where timely interventions are required due to unacceptable risk

Each year, in consultation with their provincial and territorial partners, PMRA science directorates and RAPB officers determine promotion and compliance priorities based on criteria such as risk, history of complaints, and provincial input. In 2016-17, the Atlantic Regional Office, located in Moncton, has planned targeted oversight of the industrial use of glyphosate on rights-of-way such as train corridors, power corridors, and telecommunication towers²⁷. A summary of these inspection programs is reported annually (see e.g. Health Canada 2016).

²⁷ Personal communication from Health Canada Atlantic Regional Office to OCMOH, May 30, 2016

Comparison of NB Use Patterns to PMRA Risk Assessment

The PMRA draft health risk assessment (PMRA 2015) attempts to estimate exposures to glyphosate from a comprehensive set of possible human exposure routes and to compare these to toxicological points of departure or reference doses/acceptable daily intakes derived from toxicological studies. In general, the results of these exercises will indicate the need for additional protective measures only if the estimated exposures are greater than the reference values or if sufficient margins of exposure are not met.

To put these findings into context, it is also important to understand PMRA's methodology and to determine if use patterns in New Brunswick could result in less, the same or more exposure than what was assumed in PMRA's risk assessment scenarios. **Any instances of exposures in New Brunswick that are potentially higher than what was assumed by PMRA should trigger a more thorough examination of the risk in the New Brunswick context.** Similarly, any cases where exposure controls in NB exist beyond what was assumed by PMRA should indicate that exposures in NB are likely lower than that in the PMRA scenario, and thus are of even lower risk than that determined by PMRA.

Accordingly, OCMOH staff reviewed the PMRA draft health risk assessment (PMRA 2015) in some detail. Although the assessment covers many additional areas such as environmental effects and deriving the reference values, the principal items of interest for relating to the New Brunswick context are the human exposure scenarios considered in the risk assessments. The exposure scenarios considered²⁸ by PMRA versus the expected relationship to use patterns in NB is summarized in the following table.

Glyphosate is used in forestry operations in New Brunswick more often than the Canadian average. However, OCMOH found no evidence to suggest that this poses a risk to worker safety. A specific case study was examined (see Appendix 5): the results of this study indicated that the quantities of glyphosate handled in aerial forest spraying in New Brunswick were less than the maximum quantities assumed in the PMRA risk assessment, and so the PMRA scenario is protective of New Brunswick workers in this industry.

²⁸ Where applicable (dietary, post-application, bystander, etc.), exposure and risk estimates were stratified by age and sex, and occupational exposure and risk estimates were stratified by application method

PMRA exposure scenarios	Relationship to NB context
1. Acute dietary exposure (food only and food + drinking water)	1. No reason to suspect that exposures in NB would be any different
2. Chronic dietary exposure (food only and food + drinking water)	2. No reason to suspect that exposures in NB would be any different
3. Non-occupational exposure <ul style="list-style-type: none"> a. residential use applicator b. residential post-application contact (lawns) c. post-application contact (golf course turf) d. hikers as bystanders to forestry uses, non-cropland industrial uses 	3. <ul style="list-style-type: none"> a. Exposures in NB are expected to be less, due to provincial controls on Domestic class products (e.g. no mixing) b. No reason to suspect that exposures in NB would be any different, as application rates should be similar c. No reason to suspect that exposures in NB would be any different, as application rates should be similar d. Although glyphosate is used in forestry operations in NB more often than the Canadian average (i.e. possibly more likely to encounter treated forest than elsewhere), the PMRA scenarios assume contact with a treated area. Thus, no reason to suspect that NB would be any different
4. Occupational exposure <ul style="list-style-type: none"> a. Commercial mixer, loader, applicator exposures (via a variety of application methods) b. Commercial post-application exposures <ul style="list-style-type: none"> i. Forestry (weeding/grading/tagging, transplanting, scouting, irrigation) ii. Variety of agricultural crops (weeding, transplanting, scouting, irrigation, others) iii. Non-cropland and industrial uses (scouting, irrigation, others) 	4. <ul style="list-style-type: none"> a. A case study (Appendix 5) indicated that typical quantities of glyphosate products handled by workers in aerial forest spraying in NB were less than what was assumed by PMRA. Thus, the PMRA risk assessment is protective of New Brunswick workers in this industry. b. No reason to suspect that exposures in NB would be any different, as application rates should be similar
5. Aggregate exposures <ul style="list-style-type: none"> a. Adult residential applicator + post-application + chronic dietary exposure b. Children (6 to <11 years old) and youth post-application + chronic dietary exposure c. Children <2 years old residential post-application + incidental oral (hand-to-mouth) + chronic dietary exposure 	5. <ul style="list-style-type: none"> a. Exposures in NB are expected to be less for the applicator portion due to provincial controls on Domestic class products (e.g. no mixing). Post-application and dietary should be similar, thus less overall b. No reason to suspect that exposures in NB would be any different, as application rates / diet should be similar c. No reason to suspect that exposures in NB would be any different, as application rates / diet should be similar

Questions Regarding PMRA's Assumptions in Assessing Risk

In common with other assessments (e.g. EFSA 2015), PMRA's risk assessment has also been criticized by some for the appropriateness of its methodology. At the present time the comments submitted during the 60-day public comment period have not yet been compiled and published by PMRA, so the full scope of criticisms is not yet known, but some of them have been published separately (Ecojustice et al. 2015).

OCCMOH staff are in the process of seeking clarification on these points from PMRA and other experts at the time of this writing.

Conclusions

The principal findings of this Action Plan are outlined at the beginning of this document (“Summary of Principal Findings”, pp. 5-6). In brief:

- The IARC classification is a hazard assessment, not a human health risk assessment (which would also require consideration of potential human exposures to the hazard), and previous health risk assessments of glyphosate did not consider cancer as a possible endpoint. Accordingly, OCMOH staff reviewed the status of several recent international health risk assessments
- However, scientific consensus regarding the risks posed by glyphosate is still elusive: PMRA in Canada and EPA in the United States have assessments still in progress that have been long-delayed by still-evolving information, and while the European Union assessment was completed it is highly controversial
- Uses of glyphosate in New Brunswick are similar to elsewhere in terms of what it is used for and how it is applied, but the use patterns in NB are considerably different:
 - Use in NB is largely in Forestry, followed by Industrial use, Agriculture and Landscaping
 - Worldwide usage is dominated by Agriculture (approximately 90% of all usage)
 - Glyphosate is used in forestry operations in New Brunswick more often than the Canadian average
- New Brunswick has some existing controls on glyphosate and other pesticides that can help to reduce exposures, including:
 - Permit conditions for all industrial and commercial users that make specific restrictions (such as e.g., setback distances) beyond those imposed by the PMRA pesticide label
 - Prohibitions on the sale of certain Domestic class products
- A comparison of the exposure scenarios used for risk assessment in the draft PMRA reassessment to New Brunswick’s use patterns and controls on exposure identified a few notable differences:
 - Although glyphosate is used in forestry operations in New Brunswick more often than the Canadian average, OCMOH found no evidence to suggest that this poses a risk to worker safety. A specific case study was examined which indicated that the quantities of glyphosate handled in aerial forest spraying in New Brunswick were less than the maximum quantities assumed in the PMRA risk assessment, and so the PMRA scenario is protective of New Brunswick workers in this industry.

- Exposures to users of Domestic class products in NB are expected to be less than what was assumed by PMRA, due to provincial restrictions on certain Domestic class products
- Information from other agencies was identified that can help to interpret potential risks
 - JMPR undertook a health risk assessment of potential human exposure to glyphosate residues on food and concluded that glyphosate is “*unlikely to cause cancer in people via dietary exposure*”. However, this assessment considered only one possible human exposure route
 - NCCEH is in the process of producing a synthesis of regulatory information on glyphosate and other pesticides, with consideration of exposure pathways. CAREX Canada is preparing environmental / occupational exposure estimates, which will be valuable for risk assessments in future

Appendices

Appendix 1: Overview of the IARC Classification of Glyphosate

IARC Definition of Group 2A (IARC 2006):

Group 2A: The agent is probably carcinogenic to humans.

This category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. In some cases, an agent may be classified in this category when there is inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent may be classified in this category solely on the basis of limited evidence of carcinogenicity in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A.

In brief, IARC's classification of glyphosate (IARC 2015, IARC 2016) was based on:

- “Limited” evidence of cancer in humans:
 - 4 of 14 epidemiological studies (i.e. from populations with real-world exposures) showed an increased odds ratio for one particular type of cancer (Non-Hodgkin's Lymphoma, or NHL) in exposed versus control groups
 - However, the other 10 studies on NHL (including the largest and longest such study) showed no statistically significant increases
 - No associations with any other types of cancer were noted in any of the other epidemiological studies considered by IARC
- “Sufficient” evidence of cancer in experimental animals (mostly from studies of “pure” glyphosate, meaning the active ingredient only as opposed to product formulations):
 - 4 of 8 feeding studies in mice showed statistically significant associations with various types of tumours at high doses (the other 4 studies showed no significant associations)
 - 5 of 13 feeding studies in rats showed statistically significant associations with various types of tumours (the other 8 showed no significant associations)
- “Strong” evidence for genotoxicity, both for “pure” glyphosate and for glyphosate formulations, was supported by a number of studies in:
 - Exposed humans that showed associations with micronuclei formation (3 studies) or DNA breaks (1 study)
 - Various human cell types in vitro (i.e. grown in culture) that showed associations with various indicators of DNA or chromosomal damage when exposed to glyphosate (7 of 9 studies), its principal metabolite aminomethyl phosphonic acid

- (AMPA, 2 studies) and glyphosate formulations (3 studies + 1 more with limited quality)
- Non-human mammals in vivo, for various species/tissues and various indicators of DNA or chromosomal damage
 - Glyphosate – 5 studies showed positive association vs. 6 with negative association
 - AMPA (glyphosate metabolite) showed positive association in 1 study
 - Glyphosate formulations showed positive associations in 8 studies versus 5 with negative association
 - Non-human mammalian cells in vitro, non-mammalian systems in vivo and non-mammalian systems in vitro, for various species/cell types and various indicators of DNA or chromosomal damage or mutation
 - Oxidative stress, inflammation and immunosuppression noted in many studies including human cells in vitro, non-human mammalian systems in vivo, non-mammalian systems in vivo, etc.

To reach these conclusions, IARC reviewed about 1000 studies. Some of the studies looked at people exposed through their jobs, such as farmers; others were laboratory studies on cancer and cancer related effects in experimental systems (IARC 2016).

Appendix 2: Questionnaire for Other Jurisdictions' Public Health Agencies

I am contacting you today on behalf of the Office of the Chief Medical Officer of Health (OCMOH) in the New Brunswick Department of Health. As you may know, the herbicide glyphosate has recently been classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans (Group 2A).

In light of this classification, OCMOH-NB has undertaken a project to determine what steps, if any, may be required to protect public health in our province. Our project includes a look at:

- How regulatory agencies intend to respond
- Current use patterns of glyphosate in New Brunswick compared to published risk assessment scenarios
- How other public health organizations across Canada (and elsewhere) intend to respond
-

What we ask of you:

Has your jurisdiction taken, or do you intend on taking in the future, any actions to respond to this recent change in classification?

If yes:

- What steps has your department taken or intends to take both in the short and long term?
- Are you, or a representative, available for a short telephone conversation to discuss the actions noted in question 1?

If no:

What, if anything, may trigger a change in your jurisdiction's current position on glyphosate? For example:

- Increased use of glyphosate in your jurisdiction
- Change in use of glyphosate in your jurisdiction
- Change in PMRA's (Pest Management Regulatory Agency of Canada) risk assessment or label requirements
- Regulatory changes in your jurisdiction
- Other

May I stay in contact with you or a representative of your organization for future updates on this issue? If so, please provide contact information.

Confidentiality

The information you provide will be part of an internal report presented to the Acting Chief Medical Officer of Health (Dr. Jennifer Russell).

Thank you for taking the time to participate. If you have any questions I can be reached at (phone number).

Appendix 3: Most common Glyphosate-Containing Concentrated Products in NB

12 Most widely-used Glyphosate Products in NB (alphabetical order by product name)

Product Name	PCP #	Glyphosate present as
Forza Bio 450 Silviculture Herbicide	30235	Isopropylamine Salt or Ethanolamine Salt
Forza Bio Silviculture Herbicide	30234	Isopropylamine Salt or Ethanolamine Salt
Forza Silviculture Herbicide	26401	Isopropylamine Salt or Ethanolamine Salt
Glyfos Soluble Concentrate Herbicide	24359	Isopropylamine Salt or Ethanolamine Salt
Roundup Weather Max with transorb 2 technology liquid herbicide	27487	Potassium Salt
RT/540 liquid herbicide	28487	Potassium Salt
Touchdown Total Herbicide	28072	Potassium Salt
Vantage Forestry	26884	Isopropylamine Salt or Ethanolamine Salt
Vantage XRT Herbicide	29994	Dimethylamine Salt
VisionMax Silviculture Herbicide	27736	Potassium Salt
Vision Silviculture Herbicide	19899	Isopropylamine Salt or Ethanolamine Salt
Weed-Master Glyphosate Forestry Herbicide	29009	Isopropylamine Salt or Ethanolamine Salt

PCP # = *Pest Control Products Act* product registration number

Info from (DELG 2016)

Appendix 4: NB Agriculture Statistical Review by Commodity – 2012/13

(Info from DAAF 2016)

New Brunswick agriculture is a very diverse industry with over 30 different commodities being produced. Production of different crops would utilize glyphosate to a different extent (in some cases likely not at all). The main crops (in decreasing order of hectares planted) are:

Commodity	# of Producers	Production (Ha)
Forage	1650	70,600
Grains	805	21,200
Potatoes	207	20,704
Blueberries	330	14,200
Corn	163	7,100
Soybeans	74	4,300
Oil Seeds	35	3,600
Christmas trees/ Greenery	157	2,150
Vegetables	202	778
Cranberries	28	350
Apples	25	223
Strawberries	86	132
Raspberries	85	47
Wine Grapes	16	28
Greenhouse/ Nursery	123	18
Other tree fruit	18	3
Maple Syrup	200	2,300,000 Taps

Note: Statistics are from various sources. Blueberries sales are estimates for 2014.

Source: adapted from

<http://www2.gnb.ca/content/dam/gnb/Departments/10/pdf/Agriculture/FarmingInNewBrunswick-RoadMapForNewEntrants.pdf>

Appendix 5: Case Study of Forestry Worker Exposure in NB Compared to PMRA Risk Assessment

Given that glyphosate is used in forestry operations in New Brunswick more often than the Canadian average, OCMOH staff attempted to estimate whether the worker exposure assumptions in the PMRA risk assessment scenarios (PMRA 2015) were sufficiently protective of New Brunswick workers in this industry.

The following assumptions related to worker exposure are excerpted from PMRA 2015, Table VII.1. All of these scenarios had an acceptable level of worker health protection in PMRA's calculations:

Application Equipment	Scenario	Max. Rate	Area Treated per Day
Groundboom (custom)	MLA	4.320 kg/ha	360 ha/day
Aerial	ML	4.320 kg/ha	536 ha/day
	A		
Airblast	MLA	4.320 kg/ha	20 ha/day
Mechanically pressurized handgun	MLA	0.0096 kg/L	3800 L/day
Backpack	MLA	0.022 kg/L	150 L/day
Cut stump application	MLA	0.36 kg/L	150 L/day
ROW Sprayer	MLA	0.0096 kg/L	3800 L/day

M/L = mix/load, A = apply, ROW = right-of-way

The maximum application rate is specified by the pesticide label. Therefore, the total amount of pesticide handled, and consequently worker exposure to pesticides, will be proportional to the area treated per day. Thus if workers in NB treat a greater area than these assumptions, their exposures will be higher than what was assumed by PMRA; conversely, a lesser area treated per day means that workers in NB have lower exposures than what was assumed by PMRA in determining acceptable risk levels.

The principal application method used in Forestry in NB is aerial (DELG 2016; ForestInfo.ca, undated), and Forest Protection Limited is a major supplier of aerial spraying services in NB. Information from this company regarding their 2015 spray program (FPL 2016) indicates that their crews averaged 180 hectares treated with glyphosate per day for a 35-day period in August and September 2015. Thus, worker exposure to glyphosate is expected to be lower than what was assumed in the PMRA risk assessment (536 hectares treated per day for up to 30 days), and so the PMRA scenario is protective of New Brunswick workers using the aerial application method.

Information was not readily available for other application methods, but provided that the area sprayed per day is similar to or less than the PMRA assumptions, NB worker exposures should be within what was assumed by PMRA.

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