

Consumer Product Safety

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Frequently Asked Questions on the Re-evaluation of Glyphosate

28 April 2017

Health Canada's Pest Management Regulatory Agency (PMRA) conducted a rigorous scientific re-evaluation for glyphosate based on relevant data and information from registrants, published scientific reports, federal and provincial governments, and other regulatory agencies. The proposed re-evaluation decision document was published in April 2015 for consultation (PRVD2015-01). Heath Canada considered all comments received and determined that it will continue the registration of products that contain glyphosate with changes to product labels that will provide Canadians with additional information on how to use these products safely.

The following are some commonly asked questions on the use of glyphosate in Canada. If you have any further questions regarding the glyphosate re-evaluation decision, or about any other pesticide issue, please contact Health Canada's Pest Management Information Service.

Q1. What is glyphosate used for in Canada?

Glyphosate, marketed under brand names such as Roundup[™] and Vision[™], is the most widely used herbicide in Canada. It plays an important role in weed management for both agricultural production and non-agricultural land management. Glyphosate products are used to control many weeds, including many invasive weeds and toxic plants, such as poison ivy.

Q2. What were the main findings of Health Canada's reevaluation?

Health Canada has carried out a rigorous science-based re-evaluation for pesticides containing glyphosate to ensure that they continue to meet modern standards for human health and environmental protection and provide value. The findings are that, when used according to the label instructions, products containing glyphosate are not expected to pose risks of concern to human health or the environment.

Label directions such as those described later in this document are intended to further reduce exposure. For example, as glyphosate is a herbicide, it may harm non-target terrestrial and aquatic plants. Therefore, spray buffer zones are being required to protect sensitive plants from spray drift.

Q3. What are the new label changes?

Manufacturers are required to make label changes on product labels no later than 24 months after the publication of the re-evaluation decision on glyphosate.

As a result of the re-evaluation, the Department is requiring the following information to be conveyed through statements on labels:

Human Health

- To protect commercial and residential applicators: glyphosate is not to be applied using hand-wicking or hand-daubing methods, which involve applying the herbicide directly by hand, or with a hand-held tool, on individual plants.
- To protect workers entering treated sites: a restricted-entry interval of 12 hours is required for agricultural uses.
- To protect bystanders: a statement is required indicating that the product is to be applied only when the potential for drift to areas of human habitation or areas of human activity, such as houses, cottages, schools and recreational areas, is minimal.

Environment

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

Q4. What information did PMRA consider during the reevaluation?

PMRA considered relevant data and information from registrants, published scientific reports, federal and provincial governments, and other regulatory agencies. Rigorous scientific evaluations were conducted to determine whether glyphosate would cause any negative effects to people, animals, birds, insects, plants as well as on soil and water, when used according to label directions.

Q5. What other ingredients are in pesticides that contain glyphosate?

Pesticides, including glyphosate products, are marketed in different formulations, such as solutions and granules. Other substances called formulants are intentionally added to pesticides to improve how they work, such as making them more soluble or spreadable so they can be more effective in destroying weeds. Both the active ingredient glyphosate and its formulated products were considered during the re-evaluation.

Certain glyphosate products also contain polyethoxylated tallow amines (POEA), which function as surfactants. No risk of concerns to human health or the environment were identified provided that products contained no more than 20% POEA by weight and proposed label directions (including larger spay buffer zones for products that contain POEA) are followed. All currently registered glyphosate end-use products in Canada meet the 20% limit.

Q6. Was the public consulted on the glyphosate reevaluation decision? What did Health Canada do with the comments received?

Health Canada's re-evaluation program ensures that registered pesticides regularly undergo re- evaluation, using internationally accepted assessment techniques and current scientific information. This is a legal requirement under the *Pest Control Products Act*.

As part of this process, Health Canada published the proposed re-evaluation decision on glyphosate for public consultation in 2015. Comments were received from various stakeholders including registrants, growers, and the public. All comments received during the consultation period were taken into consideration. These comments and new information resulted in only minor revisions, which are reflected in the final re-evaluation decision.

Q7. Why does Health Canada consider glyphosate as unlikely to be a cancer risk while the World Health Organization's International Agency of Research on Cancer has deemed glyphosate as "possibly carcinogenic to humans?"

Hazard classifications are not the same as health risk assessments. Hazard classifications established by the World Health Organization do not take into account the levels of human exposure, which determines the actual risk. Pesticides are registered for use in Canada only if the level of exposure to Canadians does not cause any harmful effects, including cancer.

To reach its decision, the PMRA applies risk assessment methods that consider sensitive population subgroups in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants).

As part of the re-evaluation decision for glyphosate, Health Canada reviewed the dietary exposure to glyphosate and found that the levels found in food would not be a health risk to Canadians.

Q8. What are the findings of other jurisdictions on glyphosate?

In November 2015, the European Union Member States finalized their reassessment of glyphosate, finding that glyphosate is unlikely to pose a carcinogenic hazard to humans. In May 2016, the United Nation's Food and Agriculture Organization and World Health Organization Joint Meeting on Pesticide Residues concluded that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet. In March 2017, the European Chemical Agency released their determination that glyphosate is not classified as a carcinogen, which will be forwarded to the European Commission for final decision.

Currently, no pesticide regulatory authority in the world, including Health Canada, considers glyphosate to be a carcinogenic risk of concern to humans.

In December 2016, the United States Environmental Protection Agency Scientific Advisory Panel discussed the cancer potential of glyphosate. The final meeting report of the panel, Meeting Materials for the December 13-16, 2016, Scientific Advisory Panel, was posted on March 17, 2017. The PMRA is continuing to monitor activities of regulatory organizations, including the United States Environmental Protection Agency review of the panel recommendations and final determination regarding the potential carcinogenicity of glyphosate.

Health Canada will take appropriate action if human health or environmental risks of concern are identified.

Q9. Why has Canada come out with a decision to continue registration of glyphosate products ahead of Europe and the United States? Aren't you working together?

Canada works closely with its international counterparts to ensure that regulations for pesticides are aligned internationally. During the reevaluation of glyphosate, Health Canada worked cooperatively with the United States Environmental Protection Agency by sharing study reviews, as well as reviews of relevant published literature. However, consistent with other joint activities, each country conducts their own risk assessments, taking into consideration country-specific legislation and policies. This is why decisions are not always published at the same time.

Health Canada is aware of the recent United States Environmental Protection Agency's Scientific Advisory Panel report on glyphosate. The Department will continue to monitor regulatory activities from the United States, including the Environmental Protection Agency's review of the Scientific Advisory Panel recommendations, and their final determination regarding the potential carcinogenicity of glyphosate.

Health Canada will take appropriate action if human health or environmental risks of concern are identified.

Q10. Does glyphosate affect the traditional diet of First Nations communities?

The First Nations traditional diet may consist of vegetation foraged from the land and forest instead of farmed vegetation. Depending on the province, each provincial jurisdiction may use pesticides, including glyphosate, to treat invasive weeds on the land. Forestry management falls under provincial jurisdiction.

Based on the dietary risk assessment conducted by Health Canada, the Department can extrapolate that the anticipated residues of glyphosate in edible forest vegetation would not be of concern when ingested as part of the traditional diet.

Q11. There are so many published reports regarding the safety of genetically modified foods in relation to the use of glyphosate products. What is Health Canada's position on this topic?

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

Q12. What are the Maximum Residue Limits for glyphosate?

Health Canada establishes Maximum Residue Limits (MRLs) for pesticide residues in all foods, including genetically modified foods, regardless of

whether they are grown in Canada or imported. Canadian MRLs are set only after an extensive review of the scientific information and after a thorough risk assessment confirms that there are no health concerns to all segments of the population (including pregnant and nursing women, infants, children and seniors), when all possible food sources are eaten every day, over a lifetime. MRLs are set for each pesticide-crop combination and are well below levels that could pose a health concern. For more information, visit the Health Canada website on Maximum Residue Limits for Pesticides.

Q13. Are the levels of glyphosate found on food in Canada considered safe? How are the Maximum Residue Limits enforced?

Yes, based on the data and information Health Canada reviewed, the Department has assessed dietary risks and found that the levels present are not a risk of concern for human.

The Canadian Food Inspection Agency (CFIA) is responsible for monitoring pesticide residues in food. The CFIA works closely with Health Canada to ensure that foods available on the Canadian market comply with the MRLs. Activities include testing of fresh fruits, vegetables, grains, pulses, and oil seeds that are domestically produced, as well as monitoring of imported foods. To date, the results from monitoring pesticide residues in food show a high degree of compliance with the MRLs.

In 2015, the CFIA tested a large number of samples for glyphosate, consisting of a wide variety of food commodities. The CFIA anticipates having its full analysis completed by spring 2017, and the summary of their report will be available on the CFIA website.

Q14. In the United States, a non-governmental organization (Moms Across America) claimed that glyphosate was detected in breast milk. How was this viewed by Health Canada?

Trace levels of pesticide residues can occur on food including breast milk. However, these are at extremely low levels, and well below the amount that would pose a health concern. (Trace levels are in the parts per billion or parts per trillion range, well below most glyphosate Maximum Residue Limits (MRLs) which are in parts per million).

Glyphosate MRLs for various food commodities range from 0.08 ppm to 35 ppm, depending on the commodity. MRLs for pesticides can be found by searching the Canadian Pesticide MRL Database on the Pesticides and Pest Management portion of Health Canada's website.

The Moms Across America article cited health effects in rats exposed to low levels of glyphosate. These findings were from a study that was internationally discredited by various international organizations and regulatory authorities, including Health Canada, and later retracted by the original publishing journal. For more information, you can read the <u>Health Canada and Canadian Food Inspection Agency statement on the Séralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603.</u>

Q15. There are reports claiming that use of glyphosate may affect human health by affecting gastrointestinal tract and its microbiome. What is Health Canada's view on this claim?

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

The risk assessment conducted by the PMRA includes consideration of clinical signs of toxicity on the gastrointestinal tract and is protective of potential effects on the gastrointestinal tract.

Q16 What is the impact of glyphosate use on beneficial insects and bees as well as amphibians?

Health Canada has conducted a detailed analysis of relevant studies to determine the impact of glyphosate use on pollinators, beneficial insects and amphibians. It was determined that, when used according to label directions, glyphosate is not expected to pose a risk of concern. Buffer zones calculated for the protection of more sensitive aquatic organisms provide additional protection for amphibians.

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