Consumer Product Safety

Proposed Re-evaluation Decision PRVD2015-01, Glyphosate

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Pest Management Regulatory Agency
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This page is a summary of the consultation document. If you would like to comment, please request the full consultation document.

To obtain a full copy of Proposed Re-evaluation Decision PRVD2015-01, *Glyphosate* please contact our publications office.

Should you require further information please contact the Pest Management Information Service.

Summary

Table of Contents

What Is the Proposed Re-evaluation Decision?

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

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

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

time.

This proposal affects the products containing glyphosate registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

Proposed Re-evaluation Decision PRVD2015-01, *Glyphosate* is a consultation document that summarizes the science evaluation for glyphosate and presents the reasons for the proposed re-evaluation decision. It also proposes new risk reduction measures to further protect human health and the environment.

The information in Proposed Re-evaluation Decision PRVD2015-01, *Glyphosate* is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of glyphosate.

The PMRA will accept written comments on Proposed Re-evaluation Decision PRVD2015-01, *Glyphosate* up to 60 days from the date of publication of PRVD2015-01. Please forward all comments to Publications by using this form, Comment Form (PDF fillable/saveable - 1.14 M).

If you are using Google Chrome, download the form before completing it. Once completed, submit the form by email.

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

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

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

For more details on the information presented in this summary, please refer to the Science Evaluation of Proposed Re-evaluation Decision PRVD2015-01, *Glyphosate*.

What is Glyphosate?

Glyphosate is a non-selective herbicide registered for post-emergence control of a wide spectrum of weeds including annual and perennial broadleaf and grassy weeds, weedy trees and brush. It is registered under various forms including glyphosate acid, glyphosate isopropylamine or ethanolamine salt, glyphosate mono-ammonium or diammonium salt, glyphosate potassium salt and glyphosate dimethylamine salt. Another form, glyphosate trimethylsulfonium salt, was voluntarily discontinued by the registrant and therefore is not included in the current re-evaluation.

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.

Glyphosate products are formulated as solutions, pastes or tablets and can be applied using ground or aerial equipment. Some special application techniques are also used.

Health Considerations

Can Approved Uses of Glyphosate Affect Human Health?

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

Potential exposure to glyphosate may occur through the diet (food and water), when handling and applying the products containing glyphosate, or by entering treated sites. When assessing health risks, two key factors are considered:

- the levels at which no health effects occur in animal testing and
- the levels to which people may be exposed.

The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when glyphosate products are used according to label directions.

In laboratory animals, glyphosate was of low acute oral, dermal and inhalation toxicity. Glyphosate did not cause skin irritation or an allergic skin reaction. It was severely irritating to the eyes.

Short and long term (lifetime) animal toxicity tests, as well as numerous peer-reviewed studies from the published scientific literature were assessed for the potential of glyphosate to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints used for risk assessment included clinical signs of toxicity and developmental effects. There was no indication that the young were more sensitive than the adult animal. The risk assessment approach ensures that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

The World Health Organization's (WHO) International Agency for Research on Cancer (IARC) recently assigned a hazard 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.

Residues in Food and Water

Dietary risks from food and water are not of concern.

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

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

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

Canadian MRLs for glyphosate are currently specified for a wide range of commodities (MRL database). Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under Subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues do not exceed 0.1 ppm. The current MRLs for glyphosate can be found in Appendix VII of this document. Separate MRLs have been established for the trimethylsulfonium (TMS) cation, the major metabolite of the glyphosate-TMS salt, in/on a variety of commodities. Given that all glyphosate-TMS-containing products have been discontinued, it is proposed that all MRLs for the TMS cation be revoked.

Risks in Residential and Other Non-Occupational Environments

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

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

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

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

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

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

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

Occupational Risks from Handling Glyphosate

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

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

Postapplication risks are not of concern for all uses.

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

Polyethoxylated Tallow Amines

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

Environmental Considerations

What Happens When Glyphosate Is Introduced Into the Environment?

When used according to proposed label directions, glyphosate products do not pose an unacceptable risk to the environment. Labelled risk-reduction measures mitigate potential risks posed by glyphosate formulations to non-target plants and freshwater/marine/estuarine organisms.

When glyphosate is released into the environment, it can enter soil and surface water. Glyphosate breaks down in soil and water and is not expected to persist for long periods of time. Glyphosate produces one

major transformation product in soil and water, aminomethyl phosphonic acid (AMPA), which can persist in the environment. Carryover of glyphosate and AMPA into the next growing season is not expected to be significant. Glyphosate and AMPA are not expected to move downward through the soil and are unlikely to enter groundwater.

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

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

In the terrestrial environment the only area of risk concern identified from the available data was for terrestrial plants and therefore spray buffer zones are required to reduce exposure to sensitive terrestrial plants.

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

Glyphosate, AMPA and POEA do not meet all Toxic Substances Management Policy (TSMP) Track 1 criteria and are not considered Track 1 substances. Other than incident reports of damage to plants, there are currently no environmental incident reports involving glyphosate in Canada.

Value Considerations

What is the Value of Glyphosate?

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

Glyphosate is an important herbicide for Canadian agriculture, for the following reasons:

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

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

Proposed Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed

by law. As a result of the re-evaluation of glyphosate, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- To protect workers entering treated sites a restricted-entry interval of 12 hours is proposed for agricultural uses.
- 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.

Environment

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

What Additional Scientific Information is Being Requested?

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

Next Steps

Before making a final re-evaluation decision on glyphosate, the PMRA will consider any comments received from the public in response to Proposed Re-evaluation Decision PRVD2015-01, *Glyphosate*. A science-based approach will be applied in making a final decision on glyphosate. 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.

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