

Re-Evaluation of Glyphosate

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YOUR HEALTH AND SAFETY... OUR PRIORITY.



Re-Evaluation of Glyphosate

Presentation Outline

- Regulatory Requirement
- Acceptable Risk
- Re-Evaluation Program
- The Risk Assessment
- Glyphosate Proposed Re-Evaluation Decision PRVD2015-01
- References where to find them

Regulatory Requirement

- The PMRA is responsible for administering the *Pest Control Products Act* (June, 2006) on behalf of the Minister of Health.
- Primary mandate of PMRA: “to prevent unacceptable risks to people and the environment from the use of pest control products.”
- Registered products will be re-evaluated (scientific re-assessment) every 15 years

What is “Acceptable” Risk?

Acceptable risk: Reasonable certainty of no harm

- to health, future generations and environment
- from use or exposure
- when used according to label directions

[As defined in *PCPA* s. 2(2)]

Purpose of Re-evaluation

- Scientific standards change with time
 - New study protocols – improved methodology
 - Improved analytical techniques
 - New data for use in assessment
 - Risk assessment methodologies and theories evolve
- Confirm uses, supported by the Registrant
- Bring active ingredient and uses up to modern requirements/standards
- Risks from old products are mitigated to current standards or removed from the market

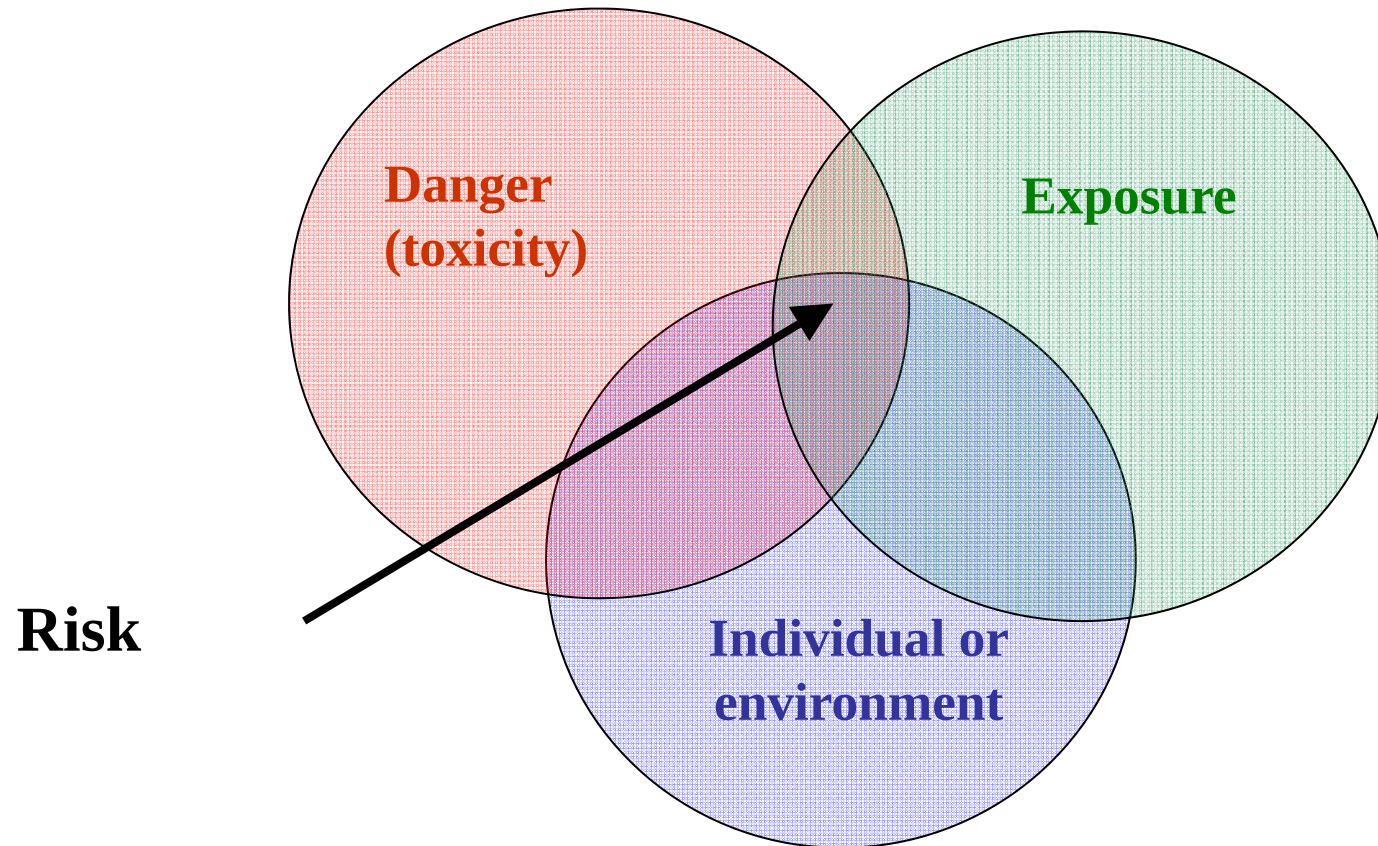
The Risk Assessment

Hazard (toxicity) & exposure must be integrated to understand risk

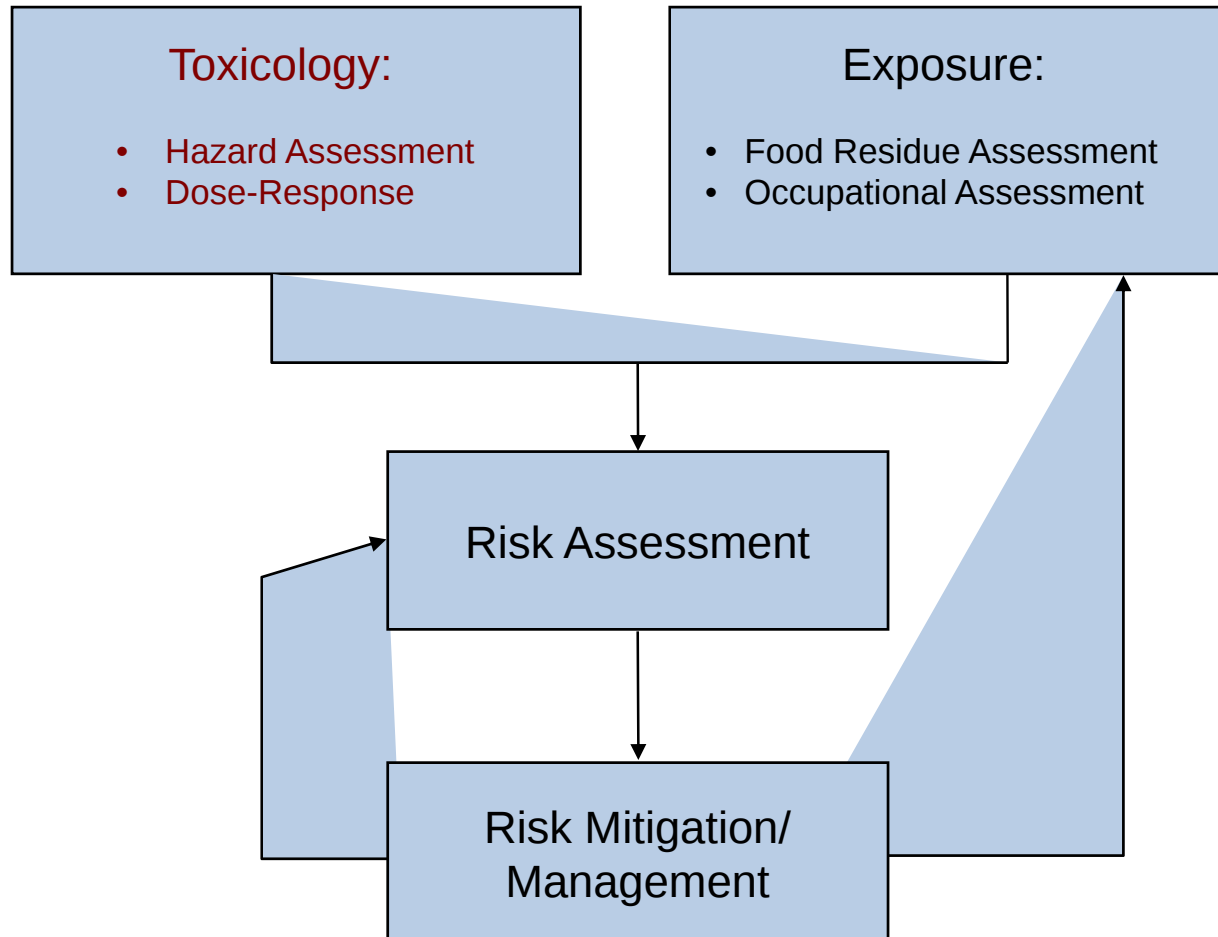
- Most substances have the potential to cause an adverse effect at high enough doses, but there is usually a lower dose where no harmful effect will occur
- Generally, as the amount of exposure increases, so does the risk of a toxic effect
- Health risk assessment puts a strong emphasis on determining both the amount and duration of people's exposures, including sensitive populations
- Risk assessment approach ensures that the level of human exposure is well below the lowest dose at which effects occurred in animal tests

Definition of Risk

$$\text{Toxicity} + \text{Exposure} = \text{Risk}$$



Risk Assessment Paradigm



Risk From Pesticide Use

- Formulation – concentrate, granules, powders
- Method of application
- Application rate
- Duration and frequency of application
- Use of PPE
- Knowledge/attitudes of applicator

Occupational Exposure: Risk Management

- Limit number or rate of applications
- Packaging modifications
 - (water soluble package)
- Label improvement
- Restrict uses (chlorpyrifos, diazinon)
- Cancel / discontinue or amend uses

ZP TRACKING POWDER

KILLS HOUSE MICE

REGISTRATION NO.: 15368 PEST CONTROL PRODUCTS ACT

RESTRICTED

DANGER  POISON

GUARANTEE:
Zinc Phosphide.....10%

READ THE LABEL BEFORE USING
KEEP OUT OF REACH OF CHILDREN

NET CONTENTS: 11.36 kg (25 lbs.)

Manufactured by: Bell Laboratories, Inc., 3699 Kinsman Blvd., Madison, WI 53704 USA
Tel. 608-241-0202

NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

NATURE OF RESTRICTION: Only to be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs.

SELECTION OF TREATMENT AREAS: Determine dry, acid-free areas where mice will most likely pick up ZP Tracking Powder on their feet or fur and ingest it during grooming. Generally, these areas are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, in spaces between floors and walls, or in locations where rodents or their signs have been observed. Remove goods piled directly on floor and place on skids. Use boxes or other obstacles to force rodents to travel through constricted areas.

This Section For Product Label Identification Purposes Only:
ZP Tracking Powder Kills House Mice, PMRA Reg. No. 15368, Container Label, 121507
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Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

I
Proposed Re-evaluation Decision

PRVD2015-01

Glyphosate

(publié aussi en français)

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Canada

Overview

- Proposed decision – continued registration
- Does not pose unacceptable risk to human health or the environment when used according to the proposed label directions
- Extensive data used from registrant, published scientific reports, information from other regulatory agencies, and any other relevant information
- Glyphosate is a glycine – amino acid – derivative that disrupts an enzyme found only in plants

PRVD2015-01

Health Risk Assessment

- In lab animals, glyphosate was of low acute toxicity
- Severely irritating to the eyes – PPE found in Precautions on the label mitigates this
- Glyphosate is poorly absorbed and mostly eliminated unchanged from the body
- Small amounts breakdown to AMPA – aminomethyl phosphonic acid, which is of no greater toxicity than glyphosate
- Not genotoxic, not a reproductive toxin and not neurotoxic
- Overall weight of evidence indicates that glyphosate is unlikely to pose a human cancer risk – this is consistent with all other pesticide regulatory authorities world-wide
- Residential and bystander risk was not of concern
- Risk to workers was not a concern – **Read and follow the label directions**

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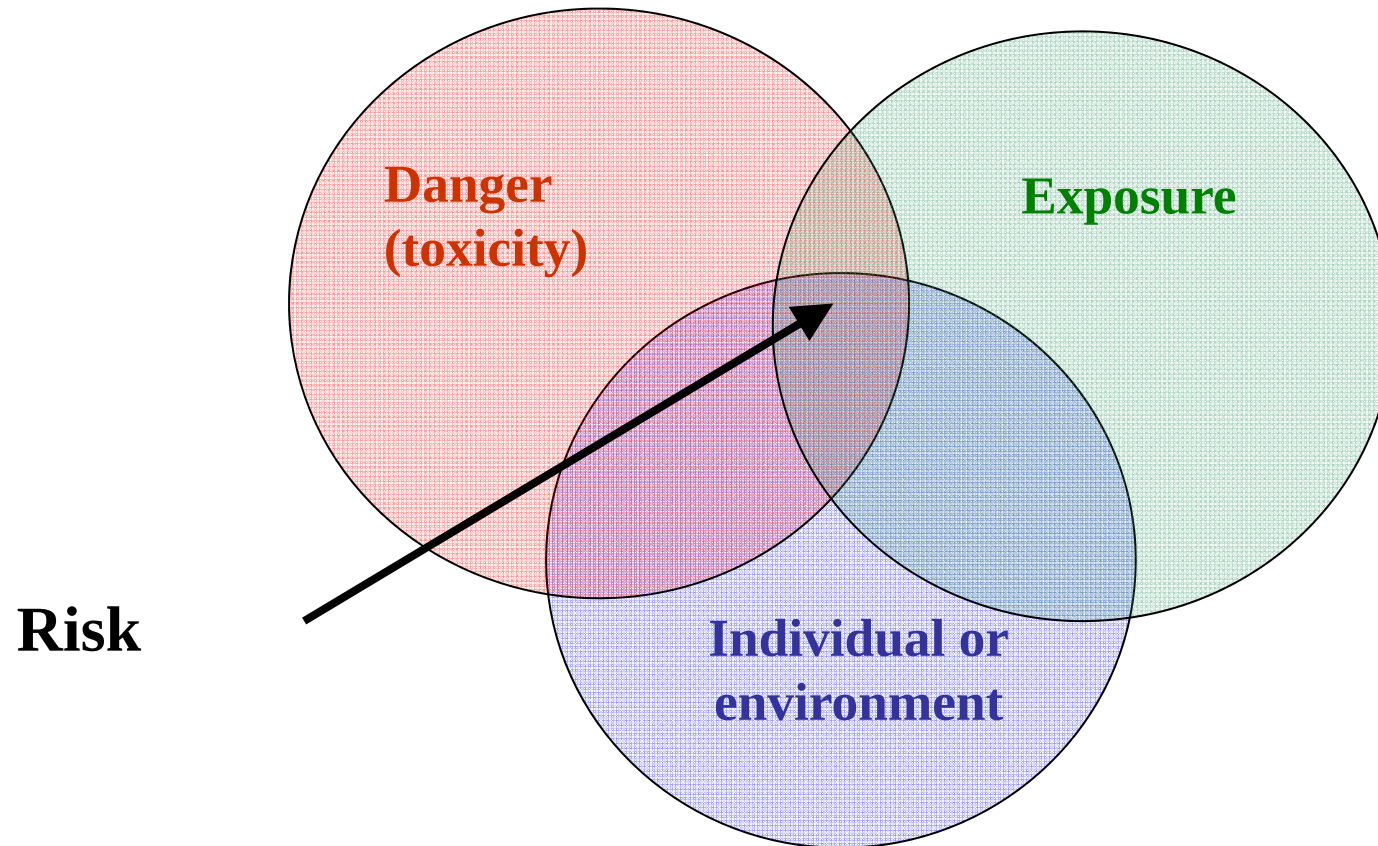
IARC (WHO)

- World Health Organization's International Agency for Research on Cancer
- Hazard classification of glyphosate – probably carcinogenic - March 2015
- Hazard classifications are not health risk assessments
- Levels of human exposure, which determines risk, were not taken into account
- Pesticides are registered for use in Canada only if the level of exposure to Canadians does not cause any harmful effects, including cancer
- Identification of a hazard may be offset by the fact that the potential for human exposure is considered to be sufficiently low so as not to pose a risk of concern to human health
- Currently, no pesticide regulatory authority in the world considers glyphosate to be a carcinogenic risk

PMRA factsheet, March 2105
Proposed Re-evaluation Decision – PRVD2015-01

Definition of Risk

$$\text{Toxicity} + \text{Exposure} = \text{Risk}$$



Environmental Risk Assessment

- When used according to label, no unacceptable risk to the environment
- Label mitigates risk posed to non-target plants and freshwater / marine / estuarine organisms – use of buffer zones
- Glyphosate breaks down (predominately microbial) in soil and water and is not expected to persist for long periods of time
- Adsorbs tightly to soil and is not expected to move downward in the soil and is unlikely to enter groundwater
- Negligible risk to fish and amphibians – mitigated by buffers
- Not acutely toxic to bees – contact or oral
- Risk to algae, plants – mitigated by buffers

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POEA

- Polyethoxylated Tallow Amines
- A family of several compounds used as surfactants in many glyphosate products
- No human health concerns identified
- POEA, at high concentrations, is toxic to aquatic organisms but not persistent
- Assessment considered that any registered products contained no more than 20% POEA by weight
- Risks are mitigated by the amount of POEA in the product and label directions – buffer zones

PRVD2015-01

Label Changes

- **Appendix XII**
 - 12 hr REI
 - Drift precautions
 - Precautions re wind, rain, run-off
 - Buffer Zones
-
- **Decision is expected March 2017**
 - The decision document will have responses to the comments submitted in response to the PRVD2015-01

Resources

- Glyphosate – Proposed Re-evaluation Decision PRVD2015-01
http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prvd2015-01/prvd2015-01-eng.php
- Carcinogenicity Classification of Five Pesticides by the International Agency for Research on Cancer (IARC) March 2015
http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_fact-fiche/carcinogenicity-cancerogenicite-pesticides/index-eng.php
- EPA <https://www.epa.gov/pesticides>
- Glyphosate Issue Paper: Evaluation of Carcinogenic Potential
https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcinogenic_potential.pdf
- IARC <http://www.iarc.fr/>
- NPIC – National Pesticide Information Center
<http://npic.orst.edu/factsheets/glyphogen.html> General Fact Sheet
<http://npic.orst.edu/factsheets/archive/glyphotech.html> Technical Fact Sheet
- Frontline: Frequently Asked Questions (FAQs) On the Use of Herbicides in Canadian Forestry – D.G Thompson, D.G. Pitt Technical Note No. 112

Health Canada Pesticide Labels App





Pesticide Labels
Étiquettes de pesticides

English Français

Terms and Conditions Avis

Version 1.0.0

1

Search for any registered pesticide's label using a full text search, or by using any of the Advanced Search options.

2

From the results of your search, you can filter within the results, save any of the labels as a Favourite, or save your search.

4

Find your Favourite labels & Saved searches in the Favourites tab.

Should you find yourself in an area without Internet access, any labels saved as a Favourite will be downloaded to your device for viewing while offline!

3

Clicking on any of the results gives more details on the pesticide product, allows you to save it as a Favourite, and view a PDF version of the label.

The **FREE** Pesticide Labels App is available for iOS, Android & the Amazon App Store for Blackberry or scan the QR code from your device.






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