Glyphosate

Chemical name	Pronunciation	Chemical class	Use
Glyphosate	GLY-fo-sate	Phosphanoglycine	Broad-spectrum herbicide
Mode of Action: Group M herbicide. Inhibits 5-enolpyruvyl shikimate-3 phosphate (EPSP) synthase			

Issue

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is aware of recent international decisions concerning glyphosate.

Products containing glyphosate are registered for use in Australia, and APVMA approved products containing glyphosate can continue to be used safely according to label directions. Australian law requires appropriate warnings on product labels, which include relevant poisons scheduling, first aid, and safety directions detailing personal protective equipment when handling and using products containing glyphosate. The APVMA reminds users of the importance of following all label instructions.

As the national regulator for agricultural chemicals, we continue to track and consider any new scientific information associated with the safety and effectiveness of glyphosate, including information from other regulators.

In 2016, following the IARC assessment, the APVMA considered glyphosate and found no grounds to place it under formal reconsideration again. The APVMA completed a review of glyphosate in 1997, which set Australia's health-based guidance values at a level that remains protective. Different labels have different purposes. More information on how to read a label can be found on our website.

Concerns have been raised about human exposure to the common herbicide glyphosate, after a 2015 International Agency for Research on Cancer (IARC) assessment, which has classified glyphosate in a group of chemicals that is 'probably carcinogenic to humans based on a strength-of-evidence assessment.

In 2016, following the IARC assessment, the APVMA considered glyphosate and found no grounds to place it under formal reconsideration. Glyphosate is registered for use in Australia, and APVMA approved products containing glyphosate can continue to be used safely according to label directions.

Glyphosate is a broad-spectrum herbicide that works by inhibiting an enzyme found in plants; this enzyme is not found in humans. There are around 500 products containing glyphosate registered for use in Australia. Glyphosate has been registered for use in Australia for over 40 years.

The APVMA's approach to chemical risk

All glyphosate products registered for use in Australia have been through a robust chemical risk assessment process and are safe to use, provided they are used as per the label instructions.

As Australia's agvet chemical regulator, it is the role of the APVMA to consider all relevant scientific information when determining the likely risk before registering a product. This includes considering the impact on human health and worker safety—including long- and short-term exposure to users, as well as environmental and animal health risks, and residues in food.

It is the role of regulators to determine whether products used according to label instructions could result in a level of exposure that poses an unacceptable risk.

Consistent with regulators in other countries, the APVMA uses a risk-based, weight-of-evidence assessment, which considers the full range of hazards and risks—including studies of cancer risks—and how human risk can be minimised through instructions for use and safety directions.

Chemical risk assessment = hazard assessment x exposure assessment.

Hazard assessment: an assessment of the data related to the intrinsic potential of an active constituent and/or formulated product to cause harm.

Exposure assessment: the process of estimating or measuring the magnitude, frequency and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and uncertainties in the assessment.

A hazard assessment considers only the potential to cause harm. It does not determine whether or not the harm will occur. It also does not determine the likelihood of harm occurring in real-world situations.

The hazard assessment is an early step in determining whether a chemical poses an undue risk. A risk-based assessment builds on the hazard-based assessment by determining the likelihood of harm occurring and the severity of the harm should it occur if a product is used according to the instructions on the approved product label.

In the weight-of-evidence assessment used by regulators, relevant observations are validated because different investigators reproduce them independently. A weight-of-evidence assessment considers both the number of studies reporting a particular conclusion and the quality of the study design and data analysis.

> **A strength-of-evidence assessment can be based on a single study, even if the study protocol has limitations or does not comply with internationally accepted regulatory protocols, or if the results are not consistent with observations made in other well-designed studies. Regulators do not use strength-of-evidence assessments.**

New studies, assessment reports, and scientific opinions on approved pesticides or veterinary medicines are generated regularly. The APVMA evaluates the scientific merits of this information before deciding on whether a formal reconsideration—or other regulatory action—is appropriate.

Assessment of the IARC report by the APVMA

The APVMA evaluated the IARC report and other contemporary scientific assessments as part of the established chemical reconsideration nomination process specified by our legislation.

Further information on the chemical reconsideration process can be found on our website.

The APVMA conducted a weight-of-evidence evaluation that included a commissioned review of the IARC monograph by the Department of Health, and risk assessments undertaken by expert international bodies and regulatory agencies.

The review commissioned by the Department of Health was conducted in two phases. The first phase (Tier 1) identified which studies relied on by IARC should be reviewed in more detail, while the second phase (Tier 2) involved a detailed assessment of those studies.

The APVMA has concluded that glyphosate does not pose a carcinogenic risk to humans and that there are no grounds to place it under formal reconsideration. You can read the full assessment in the proposed regulatory position report on our website.

> **The current assessment by the APVMA is that products containing glyphosate are safe to use according to the label instructions.**

The APVMA continues to maintain a close watch on new assessment reports or scientific studies that indicate that this position should be revised.

The APVMA invited individuals and organisations to submit their comments and suggestions on the proposed regulatory position on glyphosate. Comments on this report were assessed by the APVMA and the Final Regulatory Position Report has been published. No scientific evidence that the APVMA has not already considered relating to the potential carcinogenicity of glyphosate was submitted during the public consultation period.

The IARC assessment explained

The report released in 2015 by IARC, an agency affiliated with the World Health Organisation (WHO), classified glyphosate as ‘probably carcinogenic to humans, following a hazard-based, strength-of-evidence assessment of publicly available scientific information.

The IARC assessment looked at the intrinsic toxic potential or ‘hazard’ of the chemical glyphosate as a cancer-causing agent only. Indoor emissions from burning wood and high-temperature frying, some shift work, and consumption of red meat are also classified as probably carcinogenic to humans and are in the same category as glyphosate. Agents classified by IARC in the highest category (carcinogenic to humans) include all alcoholic beverages, consumption of processed meat, solar and ultraviolet radiation (i.e. sunlight), diesel engine exhaust, post-menopausal oestrogen and oestrogen-progestogen therapy, outdoor air pollution, occupational exposure as a painter, and soot and wood dust.

When making an assessment of the hazards associated with these agents they did not consider actual use and exposure affects the final overall risk (risk = hazard x exposure). For example, realistic use situations, the formulation or application technology, or the risk of glyphosate causing cancer when used according to the label instructions in a registered chemical product.

As part of the regulatory process undertaken by the APVMA and pesticide regulators in other countries, a hazard assessment is just one part of the overall risk assessment required to determine the risks for people using a registered chemical product.

It is not the role of IARC to consider how a formulated chemical product is used, or how risks can be mitigated, for example, by following the safety directions on a product label. According to the IARC Preamble, the Monographs "identify cancer hazards even when risks appear to be low in some exposure scenarios." This means the findings of IARC hazard assessments cannot be directly compared with the risk assessments conducted by regulatory authorities for the purposes of approval or registration of a pesticide product—such regulatory assessments include consideration of appropriate risk mitigation measures to allow safe use.

Reviews and assessments by international experts

A joint expert task force comprising scientists from the WHO, national governments and universities has reviewed the information considered by IARC to determine whether there is a need to update previous assessments on glyphosate undertaken by the Joint FAO/WHO Meeting on Pesticide Residues (or JMPR) conducted in 2011, 2006, and 2003.

> **The JMPR is an international expert scientific group administered jointly by the United Nations FAO and the WHO, which undertakes pesticide risk assessments to establish safe limits of pesticide residues in food important for international trade. The APVMA is represented on this expert task force.**

In September 2015, the task force recommended that the JMPR undertake a full risk-based, weight-of-evidence re-evaluation of diazinon, glyphosate, and malathion.

The JMPR met in May 2016 in Geneva, Switzerland, at WHO headquarters to discuss their assessment of all three chemicals.

The summary findings of this meeting were published on 16 May 2016 and a more detailed summary report has recently been published. The JMPR concluded that while there was some evidence for a positive correlation between occupational glyphosate exposure and non-Hodgkin lymphoma in some studies, the only well-designed large cohort study found no association at any exposure level.

The JMPR further concluded that the overall weight-of-evidence indicates that glyphosate and glyphosate-based formulations are not genotoxic in mammals, even at high oral doses and is unlikely to be genotoxic to humans at likely levels of dietary exposure.

Finally, the JMPR concluded that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet. The WHO website contains some useful information that describes how the JMPR conducted their assessment of glyphosate. The full report of the JMPR assessment is available on their website.

The APVMA will continue to participate in international assessments and carefully consider assessments released by pesticide regulators in other counties.

Comparison of health-based guidance values

Organisation	Acceptable Daily Intake
Australia	0.3 mg/kg bw/day
World Health Organisation	1 mg/kg bw/day
European Food Safety Authority	0.5 mg/kg bw/day
The United States Environmental Protection Agency	1.0 mg/kg bw/day (draft chronic population adjusted dose (cPAD))

The Agricultural Health Study

The Agricultural Health Study (AHS) is a prospective study of cancer and other health outcomes in a cohort of more than 89,000 farmers and their spouses in the United States. The AHS began in 1993 with the goal of answering important questions about how agricultural, lifestyle and genetic factors affect the health of farming populations.

The study is a collaborative effort involving investigators from the National Cancer Institute, the National Institute of Environmental Health Sciences, the Environmental Protection Agency, and the National Institute for Occupational Safety and Health. It is not funded nor influenced by industry.

The study has produced a number of reports relating to glyphosate, including detailed, published reports specifically on glyphosate exposure and cancer. No clear or consistent association between glyphosate and cancer has been reported by either the Survey or by independent researchers who have evaluated the data.

Polyethoxylated tallow amines (POEAs) in glyphosate-based products

Some glyphosate-based products also contain POEAs as surfactants, which increase the absorption of glyphosate into the plant. POEAs are contained in several different industrial and agricultural products (not just those that contain glyphosate).

Following the assessment of glyphosate, concerns have been raised that POEAs may be more toxic to humans than glyphosate itself. Because of this, some international assessments of glyphosate have been criticised for assessing only glyphosate, and not the entire product.

However, it is important to note that all formulations of glyphosate are different, and contain many different additional components. Not all glyphosate products contain POEAs, and POEAs are not unique to glyphosate-based products.

The APVMA specifically assessed the potential for glyphosate alone to cause cancer, because IARC classified glyphosate (not POEAs) as ‘probably carcinogenic to humans.

Following the assessment of glyphosate in Europe, EFSA concluded that there was insufficient data to perform a comprehensive risk assessment of POEAs and recommended that the safety of POEAs to humans should be further clarified.

The APVMA is not currently aware of any scientific evidence that indicates that current approved label directions for products containing POEA are insufficient to ensure the safety of people exposed to POEAs. When the APVMA assesses a product for registration, the whole product (including all components) is assessed. This means that the approved label directions for products that contain both glyphosate and POEAs are based on an assessment of the whole product, not just glyphosate.

However, the APVMA will continue to maintain a close focus on any new assessment reports or studies that indicate that this position should be revised.

Using glyphosate products

All chemical products have instructions for safety and use on the label. The labels on glyphosate products are there for your safety and provide practical information on how to use each product.

Always read the label instructions and use only as directed. People should follow the use and safety instructions on all chemical product labels as these are designed to reduce human exposure to the chemical product. If the label has been removed or damaged, you can search the APVMA's chemical database to find the safety information about registered products and permits.

Based on current risk assessment the label instructions on all glyphosate products—when followed—provide adequate protection for users. Any supplementary advice proposed by any other jurisdiction does not replace or override the directions for use on the product label—these directions are based on a scientific risk assessment and are legally enforceable.

The states and territories are responsible for controlling the use of agvet chemicals beyond the point of retail sale, which includes investigating any potential breaches of the approved label instructions. If you are concerned that glyphosate or any other chemical product has been used inappropriately (not according to the approved label instructions), you can contact your state agency.

Scientific publications that have been considered by the APVMA

You can download a list of the publications that have been considered by the APVMA's scientists. Only those papers that are (a) human-relevant; and/or (b) relevant to the determination of human health-based guidance values OR the determination of human health-relevant hazards have been assessed in depth.

Resources

Glyphosate fact sheet—August 2019
Review of IARC Monograph 112 (Glyphosate): Tier 1—September 2016
Review of IARC Monograph 112 (Glyphosate): Tier 2—September 2016
Proposed regulatory position report—September 2016
Final regulatory position report—March 2017

Assessments of glyphosate by other regulators

- Anvisa (Brazilian Health Regulatory Agency)
- European Chemicals Agency (ECHA)
- European Commission (EC)
- European Food Safety Authority (EFSA)
- Health Canada's Pest Management Regulatory Agency (PMRA)
- Office of Environmental Health Hazard Assessment (OEHHA)
- New Zealand's Environmental Protection Authority (EPA)

- United States Environmental Protection Agency (US EPA).

URL: http://apvma.gov.au/node/13891
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The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator of agricultural and veterinary (agvet) chemical products.

We acknowledge the traditional owners and custodians of country throughout Australia and acknowledge their continuing connection to land, sea and community. We pay our respects to the people, the cultures and the elders past, present and emerging.