Glyphosate

Issue

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

> **The APVMA has completed its assessment of the IARC report and other recent assessments of glyphosate and has concluded that glyphosate does not pose a cancer risk to humans—see more information below.**

Glyphosate is a broad-spectrum herbicide which works by inhibiting an enzyme found in plants. There are around 500 products containing glyphosate registered for use in Australia. Glyphosate has been registered for use 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 material when determining the likely impacts on human health and worker safety—including long and short term exposure to users and residues in food before registering a product.

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 to people.

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

> **Chemical risk assessment = hazard assessment + exposure assessment**
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> **Hazard assessment: an assessment of the data related to the intrinsic toxicity potential of an active constituent and/or formulated product**
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> **Exposure assessment: an assessment of the likely exposure of humans and environmental organisms that takes into account how the chemical product is to be used, the type and formulation of the product, and the crops or animals to be treated**

A hazard-based assessment considers only whether an adverse outcome could occur not whether it is likely to occur when used in real-world situations.

The hazard-based assessment is the first step in determining whether a chemical poses an undue risk. A risk-based assessment builds on the hazard-based assessment by determining the likelihood and extent to which the adverse outcome will occur if the product is used according to the instructions on the approved product label.

> **In a weight-of-evidence assessment, relevant observations are validated because they are reproduced independently by different investigators/researchers. A weight of evidence assessment considers both the numbers of studies reporting a particular conclusion and the quality of the study design and data evaluation.**
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> **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.

Assessment of the IARC report by the APVMA

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

The APVMA evaluated the IARC report and other contemporary scientific assessments as part of an established chemical review nomination process.

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. You can read both of these reports on our website.

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 proposed regulatory position report on our website.

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

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

The APVMA invites persons and organisations to submit their comments and suggestions on the scientific justification for the proposed regulatory position on glyphosate. Comments on this report will be assessed by the APVMA (and partner agencies where required) before the report is finalised and the Final Regulatory Position Report is published. For more details about how to submit your comments, please refer to the proposed regulatory position report on our website.

The closing date for submissions is 28 December 2016.

The IARC assessment explained

The report released last year 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 toxicity 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 (ie sunlight), engine exhaust (diesel), 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 risk of these substances or lifestyles they did not consider how the risks can be managed in actual use situations and they did not assess 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 formulated chemical product.

It is not the role of the IARC to consider how a formulated chemical product is used, or how human exposure can be minimised by following safety directions on a product label. This means the findings of IARC cannot be directly compared to assessments conducted by regulatory authorities for the purposes of approval or registration of a pesticide product—assessments by regulators include consideration of appropriate risk mitigation measures to allow safe use.

Assessments of glyphosate by other regulators

The European Food Safety Authority (EFSA) has completed a reassessment of glyphosate as part of the European Union (EU) pesticide renewal process, which included a consideration of the IARC assessment. Using a risk-based, weight-of-evidence assessment approach, EFSA considered an extensive body of scientific evidence, including a number of studies not assessed by the IARC, to reach the conclusion that glyphosate does not cause cancer in humans.

Although the assessment of glyphosate by EFSA concluded that glyphosate is not likely to be carcinogenic in humans, a number of Members of the European Parliament (MEPs) are concerned that the assessment by IARC differs to that conducted by international regulators, including EFSA. On 28 June 2016, the European Commission (EC) extended the registration of glyphosate in Europe for 18 months, to allow the European Chemicals Agency (ECHA) to conduct an independent hazard assessment of glyphosate.

The ECHA conducts hazard assessments of chemicals and ensures that chemicals adhere with the classification, labelling and packaging regulations in the EU. The ECHA is not a regulatory risk assessment authority. The draft assessment of glyphosate by ECHA is available online for public consultation until 18 July 2016. The assessment proposed an additional hazard classification related to toxicity arising from prolonged or repeated exposure, but concluded that there was not sufficient evidence to support a carcinogenicity hazard classification of glyphosate.

In August 2016, New Zealand's Environmental Protection Authority (EPA) published a review of the evidence for carcinogenicity as a result of exposure to glyphosate. Using a weight-of-evidence approach, the EPA concluded that glyphosate was unlikely to cause cancer in humans. The full report and a summary are available on the NZ EPA website.

In 2015, Health Canada's Pest Management Regulatory Agency (PMRA) re-evaluated glyphosate as part of its standard regulatory procedure. Again using a weight-of-evidence approach, the PMRA concluded that glyphosate was unlikely to cause cancer in humans.

Currently, the United States Environmental Protection Agency (US EPA) is re-assessing glyphosate as part of its Registration Review program. As a part of that process and following the publication of the IARC, EFSA and JMPR assessments of glyphosate, the US EPA used a weight-of-evidence approach to re-assess the carcinogenicity of glyphosate. In September 2016, the US EPA published their assessment, which concluded that glyphosate does not cause cancer.

Reviews and assessments by international experts

A joint expert taskforce 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 for the purpose of establishing safe limits of pesticide residues in food important for international trade. The APVMA is represented on this expert taskforce.

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

The JMPR met on 9–13 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 will be available in mid to late-2016.

The APVMA will continue to participate in international assessments and to carefully consider assessments released by pesticide regulators in other counties such as EFSA and US EPA.

> **Reports claiming that glyphosate has been banned in some countries are incorrect.**

To date, no international regulator has banned the use of glyphosate in any country, following the IARC re-classification.

In some countries retailers have made the commercial decisions to stop supplying glyphosate or to restrict sales for certain uses. A European Union Directive requires Member States to implement National Action Plans for the sustainable use of pesticides and there are some country-specific restrictions on use, or requirements for use that relate to chemical herbicides in general. These are not specific to glyphosate and are not related to the IARC re-classification of glyphosate.

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 a number of 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 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.

Previous publications about glyphosate by the APVMA

The APVMA has published international activity on glyphosate previously:

- Chemicals in the news: glyphosate – 6 August 2013
- Glyphosate is being reviewed in the United States and Canada. Is it still safe to use? – 31 August 2010

Resources

Glyphosate fact sheet – April 2016

URL: http://apvma.gov.au/node/13891
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