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Submission on the Glyphosate Regulatory Position Final Report

The National Toxics Network (NTN) does not support the conclusion of the *Glyphosate Regulatory Position Final Report* 2016 which rejects the finding by the World Health Organisation's International Agency for Research on Cancer (IARC) that glyphosate is a 'probably carcinogenic to humans' (2A).

By rejecting IARC's finding, the APVMA then goes on conclude glyphosate does not need to be reconsidered and can continue to be used without any changes to its use patterns in Australia.

IARC findings

IARC has already answered the criticisms of its methodology and findings and addressed all of the issues raised in the APVMA's report. We are therefore submitting the IARC Q & A on Glyphosate released in March 2016 (Appendix 1) as part of this submission to counter the generalised criticisms the APVMA makes of IARC's methodology in its report.

IARC has rigorously and publically defended its decision in the wake of a global campaign to undermine its findings on glyphosate and restated that its decision was based on "limited" evidence of cancer in humans (from real-world exposures that actually occurred) and "sufficient" evidence of cancer in experimental animals (from studies of "pure" glyphosate). IARC also concluded that there was "strong" evidence for genotoxicity, both for "pure" glyphosate and for glyphosate formulations.

The APVMA says it has access to studies not seen by IARC, which enable it to come to a different conclusion. However, these unseen studies are industry-generated studies that are unpublished in the open literature and not peer reviewed. This is a very poor application of the scientific method the APVMA claims it bases its decision-making on.

By reaching a conclusion that is at odds with the world's independent and leading authority on cancer research, the APVMA is not demonstrating its superior scientific credentials, but rather it's showing to the world its in built bias and the lengths it will go to put the interests of industry above the health and welfare of the Australian people and environment.

IARC states in the Q & A on Glyphosate released in March 2016 that:

> "Many regulatory agencies rely primarily on industry data from toxicological studies that are not available in the public domain. In contrast, IARC systematically assembles and evaluates all relevant evidence available in the public domain for independent scientific review."
>
> "In the interests of transparency, IARC evaluations rely only on data that are in the public domain and available for independent scientific review. The IARC Working

Group's evaluation of glyphosate included any industry studies that met these criteria. However, they did not include data from summary tables in online supplements to published articles, which did not provide enough detail for independent assessment. This was the case with some of the industry studies of cancer in experimental animals."

Actions by other countries

Given the measures other comparable countries have and are taking in light of the IARC finding, as outlined in the APVMA's report, we can only conclude that the APVMA, and other agencies such as FSANZ, are utterly failing in their duty to protect public health and the environment by not formally reconsidering glyphosate and by not recommending that further research be conducted to determine the extent of real-life exposure to glyphosate as a result of use patterns in Australia.

Summary of actions comparable countries are taking:

USA

- In February 2016, the US Food and Drug Administration (US FDA) announced that they would begin testing for residues of glyphosate on various foods, including soybeans, corn, milk and eggs. Concurrently, the US Fish and Wildlife Service announced that they would commence an analysis in conjunction with the US EPA of the impacts of four commonly used pesticides (including glyphosate) on 1500 endangered species, which is due for completion by December 2022.

By contrast, the APVMA in its report, refers to an eight year out-of-date FSANZ Australian Total Diet Survey (2008) as evidence that there are 'no safety concerns' for Australian and New Zealand consumers, despite the fact that the FSANZ survey was based on a statistically insignificant sample size of 12 pieces of multigrain bread. Glyphosate usage in Australia has changed substantially in the past eight years since FSANZ conducted this ATDS and it is highly likely Australians and our environment are being exposed to more glyphosate. Why isn't the APVMA applying the same scientific rigor here?

Canada

- In April 2015, the PMRA published its Proposed Re-evaluation Decision (PRVD2015-01) for glyphosate. In that document, the PMRA proposed continued registration of products containing glyphosate for sale and use in Canada. However, as a condition of the proposed continued registration, new risk reduction measures were proposed for end-use products, aimed at protecting both human health and the environment.

Why isn't the APVMA also considering further risk reduction measures aimed at protecting human health and the environment?

Europe and the United Kingdom

- On 11 July 2016, Member State experts voted as a qualified majority in favour of two recommendations proposed by the EC as conditions to the registration extension, at a meeting of the Standing Committee in Plants, Animals, Food and Feed. These restrictions included:
    - an EU-wide ban on POEAs contained in some glyphosate-based formulations
    - restricted use of glyphosate-based formulations in public parks, playgrounds and home gardens and for pre-harvest application.

POEA

No such recommendations have been made by the APVMA to restrict the inclusion of POEA

in formulations, despite evidence that showed an impact to aquatic species (tadpoles) in Australia which triggered a special review of glyphosate by the then NRA in 1996 and led to some label restrictions to minimize risks. But that limited review is over twenty years ago and it is time the impacts of POEA are re-investigated as part of a reconsideration of glyphosate by the APVMA.

Tush et al (2013)[1] found that "POEA (polyoxyethylene tallow amine) is a surfactant with known toxic effects on aquatic organisms. POEA was added to the original formulation of the herbicide glyphosate to aid in its application and effectiveness at controlling weeds. U.S. Geological Survey (USGS) scientists developing methods to measure POEA in the environment have shown that it's a complex and variable mixture of related compounds, and that POEA is still a common additive in several newer agricultural and household glyphosate formulations. Since glyphosate is one of the most widely used pesticides in the United States, the findings could indicate that POEA may be widely available for transport into surface water and groundwater".

The APVMA has similarly not made any label restrictions for the use of glyphosate products in public places, playgrounds, home gardens and for pre-harvest applications.

Adverse Experience Reporting Program

The APVMA refers to its Adverse Experience Reporting Program (AERP) and the relatively low numbers of incidents (4) that were reported and confirmed between 1996 – 2013, as 'evidence' that label conditions are adequately mitigating risks associated with glyphosate.

Very few people are even aware that the APVMA has an Adverse Experience Reporting program to report incidents to and very few people are likely to report issues other that acute reactions. We also wonder why incidents from 2013-2016 , have not been included.

Recently published and peer reviewed research on glyphosate and glyphosate formulations

Glyphosate Consensus Statement

Myers, et al (2016)[2] published a consensus statement that addresses many issues the APVMA has raised in its report and also highlights areas of concern that the APVMA does not address.

The Statement of Concern considers current published literature describing GBH uses, mechanisms of action, toxicity in laboratory animals, and epidemiological studies. It also examines the derivation of current human safety standards.

It concludes that:

(1) GBHs are the most heavily applied herbicide in the world and usage continues to rise

(2) Worldwide, GBHs often contaminate drinking water sources, precipitation, and air, especially in agricultural regions;

(3) The half-life of glyphosate in water and soil is longer than previously recognized;
(4) Glyphosate and its metabolites are widely present in the global soybean supply;
(5) Human exposures to GBHs are rising;

(6) Glyphosate is now authoritatively classified as a probable human carcinogen;

[1] Tush, D, et al (2013). Characterization of polyoxyethylene tallow amine surfactants in technical mixtures and glyphosate formulations using ultra-high performance liquid chromatography and triple quadrupole mass spectrometry: Journal of Chromatography A, v. 1319, p. 80-87

[2] Myers, J.P. et al (2016), Concerns over use of glyphosate based herbicides and risks associated with exposures: a consensus statement, Environmental Health

(7) Regulatory estimates of tolerable daily intakes for glyphosate in the United States and European Union are based on outdated science.

PAN Monograph on Glyphosate

As part of our submission we are also attaching as Appendix 2, a monograph on *Glyphosate* prepared by the Pesticides Action Network International (October 2016).

The reason for this inclusion is to counter the assertion made in the APVMA's report that, "there are no scientific grounds for placing glyphosate and products containing glyphosate under formal reconsideration".

The open, scientific literature summarised in the monograph raises concerns that we believe do warrant further investigation by the regulator of pesticides as part of a reconsideration assessment.

For example:

> Recent studies show glyphosate can cause imbalances in the normal gastrointestinal microbiome, increasing vulnerability to pathogenic bacteria and influencing the response to antibiotics and intestinal functioning, in humans and animals.
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> A number of studies have demonstrated that both glyphosate and the Roundup formulation disrupt oestrogen, androgen, and other steroidogenic pathways, and cause the growth of human breast cancer cells.
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> Scientists have also found harmful effects on human cells at levels of glyphosate too low to have an herbicidal effect, some at levels similar to those found in food. These effects are amplified by the adjuvants in the Roundup formulation, which assist penetration of the cells by glyphosate. Several researchers have reported that glyphosate appears to accumulate in human cells.
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> Kidney and liver are the main target organs for glyphosate, and a wide range of adverse effects are reported from laboratory studies, including cell damage and death, DNA damage and tumours. Glyphosate is implicated in an epidemic of 'chronic kidney disease of unknown cause' (CKDu) amongst farmers in Sri Lanka, Andhra Pradesh (India), and Central America, in part because of the herbicide's ability to chelate nephrotoxic metals.
>
> Several studies indicate that glyphosate formulations may interfere with the immune system resulting in adverse respiratory effects including asthma, rheumatoid arthritis, and autoimmune skin and mucous membrane effects.

Conclusion

Unlike the USA, Canada and the EU, Australia does not have a systematic review program for pesticides. What this means in practice is that glyphosate may never come up for reconsideration in Australia.

Given that a limited review of glyphosate took place by the then NRA in 1996, and there has been a substantial increase in the use of glyphosate since that time, as well as a paucity of exposure data in Australia on dietary intake of glyphosate residues and environmental exposures, we believe it is time the APVMA reconsiders the use of glyphosate in Australia. Anything less would be negligent.

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