

13 September 2024

Correction of ABC reporting – the APVMA's proposed regulatory decision on paraquat

During August and September 2024, the ABC has published a number of articles regarding the APVMA's proposed regulatory decision on paraquat that make false or misleading claims.

The proposed regulatory decision is currently undergoing <u>public consultation</u>. All submissions made during the consultation process will be considered during the development of the final regulatory decision.

Underpinning science of the review

The article published on 11 September 2024 claims "that the science underpinning the APVMA's advice on paraquat was based on an unpublished paper funded by the maker of the chemical, Syngenta".

This statement is not correct. The APVMA considers scientific information from a variety of sources when reviewing agvet chemicals to determine their safety, efficacy and potential impact on trade, in line with our legislation. To inform the paraquat proposed regulatory decision, the APVMA considered a wide range of studies relating to paraquat, including animal and epidemiological studies, as well as the conclusions reached by the US EPA. Studies considered included scientific studies published in peer reviewed journals, and data provided by the registrants.

The APVMA makes independent, scientific decisions on the basis of the available evidence. Our decisions are made in line with Australian law and in the interests of the Australian community. The APVMA may reach different conclusions to study authors, following thorough analysis. The APVMA's analysis can be found in the Paraguat Review Technical Report.

In the same 11 September 2024 article, the ABC published a quote from the APVMA regarding experimental paraquat trials without crucial context. The APVMA acknowledges that there are experimental animal studies which have shown, that when high doses of paraquat are injected into the abdominal cavities of mice, it can result in Parkinson's like effects. The APVMA does not consider this study relevant for several reasons:

- The mice were administered the injections at extremely high dosages which far exceed exposure resulting from the use patterns authorised on product labels.
- Directly injecting paraquat bypasses a number of filtering mechanisms in the body, which can result in a higher amount of paraquat being observed in the brain. This does not accurately reflect occupational exposure to paraquat, and it is not possible to draw a parallel between the two.

This current review is in addition to the <u>2016 review</u> of paraquat, where the APVMA requested an evaluation of the toxicology of paraquat by the Department of Health. The 2016 review considered data submitted by industry and published data, as well as assessments undertaken by other pesticide regulatory agencies and the World Health Organization.

At the time of the 2016 review, the epidemiological studies available did not find a robust association between paraquat exposure and Parkinson's disease. Additional studies on workers manufacturing paraquat did not show any association with Parkinson's disease, and investigation of survivors of paraquat poisoning (who would be anticipated to have high exposures) did not show

neurotoxic effects. These findings are also supported by a <u>recent</u> <u>review</u> undertaken by the US EPA.

Importance of Personal Protective Equipment

Many of the practices described in the ABC in the Landline story are historical, and do not meet current requirements for the use of agvet chemical products.

In Australia, comprehensive PPE and safety handling procedures are required for the legal use of many agvet chemical products including paraquat. This may include the required use of a closed loop transfer system, personal masks, filtered cabins for tractors, or directing the nozzle to minimise spray drift.

The APVMA reviews the safety of agvet chemicals under the presumption that they will be used in line with the legally required label instructions. The use of proper PPE is critical to protecting the health and safety of Australian workers and any use contrary to the label instructions has not been assessed for safety.

The APVMA maintains an adverse experience reporting program (AERP) and encourages anyone who believes they have experienced problems with agvet chemical products to provide reports to the APVMA.

All Australians have the right to feel safe in their workplace. If you have been asked to use a chemical in a way that isn't safe, you should notify SafeWork Australia or the relevant authority in your jurisdiction so that this can be addressed.

Contemporary evidence

The articles published on 31 August 2024 and 11 September 2024 claim that there is "a growing number of independent studies linking paraquat to the incurable neurodegenerative condition."

This statement is misleading. Conclusions of the review conducted by APVMA, as well as the review undertaken by the US EPA, do not support the claim that there is a growing body of evidence indicating a causal link between exposure to paraquat and the development of Parkinson's disease.

Correlation and causation

The 31 August 2024 article states "The first-of-its-kind review, led by neurologist Caroline Tanner and funded by the US government, involved dozens of field researchers gathering data about the prevalence of Parkinson's disease among farmers in Iowa and North Carolina. It showed that farmers who used paraquat were 2.5 times more likely to develop Parkinson's disease than those who hadn't. Further studies by Dr Tanner found that risk went to 4.5 times if they didn't wear any protective equipment."

This statement is misleading as it was presented in isolation from all the available evidence. The Tanner study is an important piece of epidemiological work. However, it is only one of the studies that the APVMA considered before reaching a regulatory conclusion regarding whether or not there is a potential association between the use of paraquat, in accordance with the label instructions, and an increase in the possibility of developing Parkinson's Disease.

A more recent study, Shrestha et al (2020), found there was no association between paraquat use and Parkinson's Disease in the absence of head injury, although the study did identify an association where there was the presence of head injury.

Shrestha et al (2020) relied on the Agricultural Health Study (AHS) cohort, in a similar manner to Tanner et al (2011), however Shrestha used the additional years of available data, and higher numbers of cases for analysis (491 cases in Shrestha et al, in comparison to 110 cases in Tanner et al). Additional epidemiology studies have been considered by the APVMA including Kamel et al (2007), Goldman et al (2012), Kamel et al (2014) and Furlong et al (2015). As the studies used the same study population, areas of overlap have been taken into consideration.

Closing remarks

The ABC's reporting has misrepresented the APVMA's position, and the current scientific consensus. We have requested that the ABC issue a correction to clarify these points.

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