



Submission to:

THE SENATE

RURAL AND REGIONAL AFFAIRS AND TRANSPORT

REFERENCES COMMITTEE:

**Inquiry into the independence of regulatory decisions made by the Australian
Pesticides and Veterinary Medicines Authority (APVMA)**

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Organisational Background

The Western Australian Farmers Federation (Inc.) (WAFarmers) is the state's largest and most influential rural advocacy and service organisation. WAFarmers boasts a membership of over 3,500 primary production businesses and individual farmers including grain growers, meat and wool producers, horticulturalists, dairy farmers, commercial egg producers and beekeepers. Collectively our members are major contributors to the \$7.5 billion gross value of production that agriculture in its various forms contributes annually to Western Australia's economy.

a. The responsiveness and effectiveness of the APVMA's process for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators;

WAFarmers supports the APVMA's current scientific, legislative and risk-based process for reviewing and reassessing the safety of agvet chemicals in Australia. The current framework is backed by decisions that must comply and be consistent with the *Agricultural and Veterinary Chemicals Code Act 1994*. The APVMA utilises the relationship between research, regulatory science and regulation to review and reassess the safety of agvet chemicals.

Scientific-based decisions are made using modern peer-reviewed research and WAFarmers supports the APVMA's decision to use previously conducted research as part of the chemical application and review process. Through combining previous studies in conjunction with decisions based on Australian legislative requirements, this process ensures Australia's chemical registration process is efficient and avoids research duplication of already investigated scientific evidence and improves the timely assessment of chemistry up for review.

In relation to chemical reviews, new scientific study is costly. It is WAFarmers view that if previous peer-reviewed research is available from international regulators whom have recently approved a new registration or recently reviewed a chemical; there is no issue for this research to be used in conjunction with risk-based assessment methods as part of the regulatory process. These factors benefit the industry through improved efficiency of re-registration. It also encourages international regulators to work in partnership and allows research findings to be discussed on a global scale.

This risk-based process was used on the APVMA's 2016 review of glyphosate, after the International Agency for Research on Cancer (IARC) noted the herbicide as a "probable carcinogen" in 2015ⁱ. The APVMA reconsidered the safety of the herbicide, and "found no grounds to place it under formal reconsideration."ⁱⁱ

The APVMA's *Final Regulatory position: Consideration of the evidence for a formal reconsideration of glyphosate March 2017*, found that along with the numerous international assessments of glyphosate conducted by international organisations and regulatory agencies such as *Health Canada* and the *NZ Environmental Protection Authority*, and on the available epidemiological research and evidence available, there was no "convincing evidence for an association between glyphosate exposure in humans and any cancer type, as there was no consistent pattern of statistical associations that would suggest a causal relationship between glyphosate exposure and the development of cancer in adults or children (total or site-specific)."ⁱⁱⁱ Based on these finding and the knowledge of the APVMA's evidential and risk-based process, WAFarmers supports its regulatory position on glyphosate and the continued use as per label in Australian agriculture.

b. The funding arrangements of the APVMA, comparisons with equivalent agricultural chemical regulators internationally and any impact these arrangements have on independent evidence-based decision making;

The current cost-recovery funding arrangement ensures that chemical registrants pay to register products, and an annual fee is charged to maintain the chemical registration. WAFarmers views this funding model as a benefit to industry as it ensures the end-users (farmers) are not required to pay levies in the registration process.

WAFarmers finds this model appropriate and finds no grounds for the APVMA's independence to be reviewed based on the current funding framework. WAFarmers believes the current funding model of the APVMA does not give preference for the regulator to accelerate particular chemical applications from chemical manufacturers. It is of WAFarmers view that if a chemical were to be de-registered for use, than a similar chemical application from a competitor manufacturer would more than likely apply for registration to fill the market gap.

c. The roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals;

WAFarmers does not support the APVMA controlling the regulation of chemical application and usage, once a chemical is registered. The APVMA is responsible for chemical registration and regulation until the point of retail sale, after this the states and territory's control the use of chemical regulation in their respective jurisdiction. Whilst WAFarmers supports the use of chemical application as per label and industry requirements, it is important that jurisdictions retain their regulatory capability, particularly in terms of vet medicines when the use of off-label products is permitted at the discretion of a vet.

WAFarmers supports a harmonised approach to agvet chemical regulation, as long as it remains risk based. Harmonisation will improve grower compliance, and improve the overall food safety standards and place consumer confidence in Australia's production systems.

Whilst WAFarmers supports harmonisation that seeks to improve the understanding of off-label practices, it does not support harmonisation that seeks to remove current practices (i.e. different application equipment than on label), as is currently allowed in WA.

WAFarmers has concerns over the convoluted routes the APVMA and related government departments take to reach decisions; with particular reference to the veterinary chemical registration process. The current systems in place can be unpredictable, costly and inefficient due to administrative and operational inefficiencies – the process is arduous and in the case of veterinary chemical registration, many medicines used internationally have not been approved in Australia for use – WAFarmers Livestock Council urges the review of veterinary chemicals.

In regard to products which already exist within Australia, gaining access to "new" species (i.e. using Dectomax Injectable (labelled for cattle and swine) for sheep is currently achievable through individual producers working with their veterinarian. Veterinarians are allowed wide extra label prescribing rights for the benefit of their clients, however they are also professionally and financially liable for outcomes. The proposed legislative change will assist us to make some products that exist in Australia more accessible, however when a pathway to market already exists, there may not be much appetite from companies to chase label change, as it will still require substantial investment.

The APVMA recognises that whilst the current legislative definition is still relevant, it is nonetheless somewhat difficult to operate within because the issue of “sufficient economic return” is a very subjective concept. One of the recommendations from the APVMA Review of the National Permit System was to develop guidelines to assist in determining whether a particular use can be defined as a ‘minor use’.

The cost of registering products like strain specific footrot vaccines are unrealistic and uneconomical and sheep are considered to be major animal species. Trying to quantify the use of a vaccine to less than 10 percent of the total number of animals is a national basis per annum is difficult. Applicants must also supply full costs and projected incomes associated with a particular use covering a period of no less than three years. The applicant must demonstrate that based on the data in relation to the above that there is insufficient economic return to consider registration of the product and/or use. This can be a long and complex process while the applicant attempts to gather the evidence needed to support a minor use permit application and during this time more animals become infected and their welfare is compromised. WAFarmers would encourage APVMA to refine the application process for minor use permits, which could be achieved by the adoption of a digital application process, and taking a more pragmatic approach to the detailed evidence required for the application. This could be achieved by working more collaboratively with veterinaries and researchers particularly to redefine the 10 percent total animal limits.

Organisations applying for a permit on the grounds of an emergency use are required to submit detailed submissions addressing the relevant matters in this guideline. Each case is assessed by the APVMA on its merits. However, WAFarmers reinforces that in some circumstances the use of emergency permits is critical to the economic survival of the sector and any delay in gaining approval to use an agvet product could prove catastrophic for the industry. WAFarmers suggests a realistic approach needs to be put in place and utilised for specific emergency situations.

d. The need to ensure Australia’s farmers have timely access to safe, environmentally sustainable and productivity enhancing products;

WAFarmers supports and will continue to support the right of farmers to farm as they choose to produce food and fibre – farmers should have the right to access and use agricultural innovations that are available to them.

WAFarmers strongly supports any move to modernise decision-making resources and improve digital information systems use by the APVMA. Improved administrative protocols and software could be further implemented to enhance system efficiencies and increase promptness of chemical registration by applicants. In May 2018 the Australian Government announced that AU\$10.1million would be invested into the APVMA’s digital strategy^{iv}, WAFarmers urges the APVMA to consider enhancement techniques to simplify the application process of registrants, such as self-serving IT systems whereby registrants can easily access application status should be strongly considered.

Additionally, factors such as computerised chemical labelling systems, whereby electronic labels are made available for registered chemical products will ensure a more efficient process, and ensure that farmers have access to up-to-date information that can be integrated into their on-farm electronic technologies. WAFarmers believes the implementation of computerised decision-making processes by the APVMA would be a benefit to industry and should be implemented – currently the administrative framework is working against these efficiencies.

WAFarmers encourages greater clarity and transparency in relation to the APVMA’s ability to intervene with suspension, cancellation, approvals or registration of chemicals. It is important to ensure that the

APVMA is permitted to suspend registrations or product variation permits when false information is provided by an applicant. This ensures that stakeholders are provided accurate information and ensures safe handling of approved products.

Limiting “red-tape” within regulatory framework is an area WAFarmers will continue to support. The APVMA already utilises industry best practice and is renowned for its regulatory framework by international standards. WAFarmers is concerned that the inquiry into the independence of the APVMA could create unnecessary ties to overseas legislation which may adversely impact Australia’s chemical registration and review process. Should an international “trigger” occur, sparking an international regulatory review, Australia would be significantly restricted in its capability to approve or register applicants – the APVMA requires flexibility in dealing with registrations.

e. Any other related matters.

WAFarmers supports the consideration for the APVMA to be governed by a skills based independent Board in conjunction with its current operational capability. The benefits of this will allow for improved strategic planning and policy development, business development, financial arrangements and funding capability, and improved risk management systems.

Conclusion

The current scientific, legislative and risk-based process for reviewing and reassessing the safety of agvet chemicals in Australia by the APVMA is greatly supported by WAFarmers.

Whilst WAFarmers supports the APVMA and its current operations as an independent regulator; it does support the move to improve its operational efficiencies, with particular regard to application timeframes and formal process, the future enhancement of its digital IT systems requires continued ongoing investment to improve its current administrative inefficiencies. Whilst the APVMA does have operational inefficiencies, WAFarmers does respect its independence as a world-leading regulator.

ⁱ <https://monographs.iarc.fr/wp-content/uploads/2018/06/mono112-10.pdf>

ⁱⁱ <https://apvma.gov.au/node/26636>

ⁱⁱⁱ https://apvma.gov.au/sites/default/files/publication/26561-glyphosate-final-regulatory-position-report-final_0.pdf

^{iv} <https://apvma.gov.au/node/29516>