



NSW Farmers' Association
Inquiry into the independence of
regulatory decisions made by the
Australian Pesticides and Veterinary
Medicines Authority
November 2018



In brief...

Agriculture in New South Wales contributes \$15.4 billion to the state's economy;

The sector directly employs 77,700 people, or 2% of the total workforce;

Almost 1/3 of Australia's farm businesses are in New South Wales;



80% of land in New South Wales is devoted to agriculture;

The highest value crops and commodities in 2016-17 were wheat, beef cattle, horticulture and cotton.



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About NSW Farmers

A profitable and sustainable New South Wales farming sector

The NSW Farmers' Association is Australia's largest State farming organisation representing the interests of its farmer members.

Farmers across New South Wales produce more than \$15 billion worth of food and fibre every year, representing around one quarter of Australia's total agricultural output. Our state's unique geography means a wide variety of crops and livestock can be cultivated and nurtured. NSW Farmers is Australia's only state-based farming organisation to represent the interests of farmers of all agricultural commodities – from avocados and tomatoes, apples, bananas and berries, through grains, pulses and lentils to oysters, cattle, dairy, goats, sheep, pigs and chickens.

Our focus is not just on issues affecting particular crops or animals – it extends to the environment, biosecurity, water, economics, trade and rural and regional affairs. We also have an eye on the future of agriculture; we are advocates for innovation in agriculture, striving to give our members access to the latest and greatest innovations in research, development and extension opportunities. Our industrial relations section provides highly specialised advice about labour and workplace matters.

Our regional branch network ensures local voices guide and shape our positions on issues which affect real people in real communities. Members are the final arbiters of the policies of the Association – through our Annual Conference and elected forums such as Executive Council, members can lobby for the issues which matter to them and their community to become Association policy. Our issue- and commodity-specific Advisory Committees are elected by members to provide specialist, practical advice to decision makers on issues affecting the sector. We are proudly apolitical – we put our members' needs first.

In addition, NSW Farmers has partnerships and alliances with like-minded organisations, universities, government agencies and commercial businesses across Australia. We are a proud founding member of the National Farmers' Federation.

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Executive summary

NSW Farmers welcomes the opportunity to comment on the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

NSW Farmers supports the independent assessment, registration and regulation of chemicals used in agriculture and calls upon the Federal Government to adequately resource the APVMA, through financial and legislative means, to enable swifter consideration and registration of new chemicals, medicines and vaccines to ensure Australian agriculture can have access to the latest advances in chemical and veterinary medicine technology.

NSW Farmers has not seen any evidence to suggest that there is undue influence from chemical manufacturers on the decisions made by the APVMA. The cost-recovery model currently employed by the APVMA is appropriate for an agency undertaking work that is often for private benefit, notwithstanding the broader public benefit attached to agriculture, environmental stewardship, biosecurity and the prevention of disease. We also recognise the need for investment certainty in the agricultural sector to ensure that farmers have access to safe and reliable chemicals.

Agricultural and veterinary chemical products are important to the productivity of New South Wales agriculture, with at least 68 per cent of the value of NSW's crop production attributable to the use of crop protection products.¹ Glyphosate is a critical tool for those who choose to use it in their farm management. NSW Farmers acknowledges that more than 800 scientific studies have failed to demonstrate a link between glyphosate and cancer - that is why we support science-based decisions about chemical registration. Further, we are comfortable with the use of regulatory assessment from equivalent international agencies, as well as the decision not to undertake a whole-scale review of glyphosate. We strongly oppose any pesticide regulation that further erodes farmers' rights to use agricultural chemicals and that adopts additional regulatory or restrictive controls on chemicals that have satisfied the registration requirements of the APVMA.

While NSW Farmers has concerns about ongoing performance of the APVMA, we consider that major issues were sufficiently addressed in the Independent Review of Performance, and that ongoing implementation of the review's recommendations are critical to ensure that the integrity of the APVMA is recognised both inside and outside the agricultural industry.

¹ CropLife Australia, 2018. Economic activity attributable to crop protection products. Deloitte Access Economics Pty Ltd

Recommendations

NSW Farmers provides the following recommendations:

1. That the Australian Government review funding of the APVMA and potential impacts arising from reduced government funding on the agency's ability to exercise its core functions.
2. That the APVMA maintains satellite presence in Canberra to retain essential scientific capacity and manage relationships with key stakeholders.

Issues

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

Review and reassessment is timely, costly, and creates uncertainty for farmers and chemical manufacturers. A formal reconsideration process should only be initiated when new scientific information raises concerns relating to the safety or effectiveness of the pesticide or veterinary medicine, rather than being based on the sentiment of the public or decision-makers.

Reducing duplication and increasing the effectiveness of APVMA's initial assessment theoretically reduces the need for reassessment. In 2016, the Productivity Commission (PC) concluded that reform to the system of pre-market approval of agricultural and veterinary chemicals has the potential to ameliorate the market failure that presently limits optimal access to chemistry to Australian farmers.² The PC's recommendation that the APVMA should make greater use of international evidence in its assessment of chemicals provides one of the steps to reducing this burden on industry. The following excerpt from NSW Farmers' response to the draft PC report stated:

Specifically, the Association believes that the APVMA should develop systems that enable them to rely on hazard assessments, such as human toxicological assessment, where they have been undertaken by a trusted international agency that has utilised an approach that is in accordance with Australia's assessment regime. This would include Joint FAO/WHO Meeting on Pesticide Residues (JMPR), the Joint Export Committee on Food Additives and Veterinary Drug Residues (JECFA) or the Global Joint Review program as well as other recognised international jurisdictions.

While the APVMA has flagged that its policy is to accept these [assessments], it is done on a case by case basis, and requires the registrant to provide the data that was relied upon as part of the international assessment it seeks to rely upon. We are concerned that this leads to the potential entrenchment of a duplication of hazard assessment by the APVMA. This in

² Productivity Commission 2016, Regulation of Australian Agriculture, Report no. 79, Canberra.

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turn will continue to duplicate regulatory costs, failing to provide full relief to the opportunity cost of foregone optimal access to agvet chemical products.

We are pleased to see that the APVMA has recently focused on acceptance of international data, noting the direction from the CEO of the APVMA stating that “while the APVMA must make decisions based on Australian legislative requirements, APVMA officers are expected to use as much of any international assessments provided as possible.”³ The direction sets out clear expectations for assessment based on international data, and NSW Farmers believes this aligns with industry’s expectations. Greater acceptance of international assessments where appropriate will, notionally, reduce the cost of APVMA’s assessment and increase the agency’s on-time performance. The APVMA suggests that “this will allow us to develop a scheduling submission and likely get it into scheduling much, much earlier than we would if we were doing a full assessment.”⁴

As noted by NSW Farmers in our response to the PC’s draft report, while it is important to incorporate international data and assessment into the APVMA’s processes, it would not be appropriate to rely on decisions made by other regulators to approve an agricultural chemical for use in Australia, nor to undertake a formal reassessment or remove access to a product:

Beyond acceptance of international hazard acceptance and assessments utilising a co-equivalency, we reiterate our view there are clear limits to the ability to accept international regulatory decisions. Specifically, we do not accept the ipso facto use of regulatory decisions made in other jurisdictions as a valid justification for a domestic regulatory decision for chemicals used as part of agricultural production. This is likely to lead to less stable decision making and increases the risks of the politicisation of the approval of chemicals for use by the Australian farm sector due to the different tests used in overseas jurisdictions.

In saying this, there are instances where decisions of international regulators can be used to reaffirm the APVMA’s assessment of a product, particularly one that has been thoroughly investigated by the Australian regulator. We are comfortable with the process used in the APVMA’s risk review of glyphosate in 2016, including the use of international assessments.

NSW Farmers believes there are no grounds for the APVMA to undertake a reassessment of glyphosate safety, given recent assessments from equivalent regulatory bodies found that glyphosate does not pose a human cancer risk, including:

- Health Canada
- The European Food Safety Authority
- The European Chemicals Agency
- New Zealand Environmental Protection Authority
- The United States Environmental Protection Agency, and
- The Joint Food and Agriculture Organisation/World Health Organisation Meeting on Pesticide Residues.

³ CEO expectations on use of international data, standards and assessments 20 June 2018

⁴ <https://apvma.gov.au/node/27766>

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Equivalency with international agencies can remove the need for reassessment by the APVMA.

Jurisdictions with similar chemical regulation have used data to determine whether glyphosate safety should be reviewed. In New Zealand, glyphosate is not under consideration for review by the Environmental Protection Agency (EPA), which uses a screening tool to determine chemicals that should be reassessed (similar to the APVMA's own priority candidate review list). The tool lists glyphosate as very low on its priority list of reviewable chemicals.⁵ In this instance, the screening tool was peer-reviewed by the Australian National Industrial Chemicals Notification and Assessment Scheme, which determined the validity of the tool. The EPA's conclusion that glyphosate is low-priority for review should underpin the decision by the APVMA not to reassess glyphosate, particularly where its usage is similar to that in Australia.

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 model used by the APVMA essentially ensures that the financial burden of chemical registration is not directly linked to the agricultural industry or taxpayers. Registration of chemicals by a private company represents a private good, and this cost should not be fully passed on to government.

NSW Farmers does not consider that the funding model provides incentive for the APVMA to favour registration of certain chemicals; particularly in the case of glyphosate, were it to be removed from the market, the APVMA would receive income from other companies seeking to register chemicals to fill the gap in available herbicides. Further, the requirement for cost-recovery charges to be transferred from the APVMA to the Consolidated Revenue Fund, with appropriations sought annually from government by the APVMA, provides a level of quarantine between funds received and expended by the agency.

The APVMA implemented revised cost recovery arrangements in 2013. In considering its move to a cost-recovery model, the APVMA noted the significant shortfalls in agency funding:

The existing Manufacturers Licensing Scheme (MLS) licence fees only recover a small proportion of the total operating cost of the overall [Good Manufacturing Practice] GMP program. In 2010–11, the cost of operating the Manufacturing Quality and Licensing (MQL) Section, which administers the APVMA's GMP compliance assessment program, was \$1,396,794. The income received (through licence fees) over the same period was \$67,098 for the year, leaving a shortfall of \$1,329,696. Furthermore, the revenue recovered from licence fees has been progressively falling as more licences became fully paid. Currently, about 51 of 208 licensees have fully paid for their licences.

⁵ <https://www.epa.govt.nz/industry-areas/hazardous-substances/chemical-reassessment-programme/screened-chemicals-list/>

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Cost recovery arrangements that are consistent with the guidelines should recover the full cost of specific activities where cost effective, not inconsistent with government policy objectives, and not stifling competition and industry innovation. To be consistent with the guidelines, the design of the existing cost recovery arrangements for GMP activities should be revised. It is noteworthy that the full recovery of the costs of compliance with GMP will also allow a reduction in levy rates.⁶

NSW Farmers is satisfied that the APVMA's model meets the Australian Government's cost recovery guidelines that, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of those activities. The cost recovery policy promotes consistent, transparent and accountable charging for government activities and supports the proper use of public resources.⁷

Similarly, the New Zealand EPA uses a cost-recovery model, and this year introduced increased charges for chemical assessment applications after finding that charges only recovered 11 per cent of the agency's assessment costs. The consultation report summary states:

Effectively, less government funding is available for hazardous substances work supporting New Zealanders, as it is being used to subsidise application costs. In particular, less funding is available for reassessments of approvals and group standards, promoting awareness about keeping people and the environment safe when using, storing, and disposing of chemicals, and compliance monitoring and enforcement work.⁸

NSW Farmers argues that the EPA is right in saying that increased reliance on appropriations to cover assessment costs reduces the ability to undertake other critical activities, and that this is similarly the case in Australia – particularly when there is a push to have chemicals such as glyphosate reassessed.

We consider that there is scope to review the APVMA's current appropriation, and whether it remains sufficient to adequately cover core activities and deliver more reliable on-time performance. At Budget Estimates in May 2018, APVMA Chief Executive Officer Dr Chris Parker stated that *"I'm losing \$3½ million a year, and I no longer have any reserve sitting in there,"* and noted that the APVMA had engaged PwC to undertake revenue modelling. The then Assistant Minister for Agriculture and Water Resources, Senator the Hon Anne Ruston, stated:

"[T]he fact that this organisation is losing money every year and the fact that we haven't been able to achieve the standards or the benchmarks that we'd set ourselves around timeliness of registrations et cetera speak for themselves when it comes to the need to come

⁶ Cost recovery of compliance with compliance with good manufacturing practice - Supplementary discussion paper

⁷ https://www.finance.gov.au/sites/default/files/australian-government-cost-recovery-guidelines_0.pdf

⁸ <https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Fees-consultation-2018/Quick-Summary-Our-Fees-are-Changing.pdf>

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up with a system of operation of this organisation that is going to be able to deliver those outcomes, because they obviously haven't been delivered to date.”⁹

The total drawdown of reserves and continual losses are of obvious concern to NSW Farmers and wider industry. While we await the findings of revenue modelling, we also call on the Australian Government to ensure the APVMA is adequately funded to undertake its statutory obligations.

RECOMMENDATION: That the Australian Government review its funding of the APVMA and potential impacts on the agency’s ability to exercise its core functions.

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

NSW Farmers notes that there are discrepancies between governments regarding chemical regulation, and we support harmonisation, particularly where it achieves more uniform and consistent chemical regulation across all states. It is also important that jurisdictions retain the ability to regulate certain chemical usage as per their individual industry and environmental requirements, rather than the APVMA controlling all usage regulations.

A timely example of this is off-label chemical use. Off-label and minor use mechanisms have been an important and valuable resource to allow Australian farmers access to the chemicals they need to produce safe food in an environmentally responsible manner. NSW Farmers supports an off-label use system that reinforces the efficient and effective use of chemical products by farmers as a practical solution, provided it is based on a model incorporating the merits of all state off-label use systems and that chemicals are used with due care.

In seeking harmonisation with other states (namely Victoria), our members have indicated a concern over the competitive production disadvantage NSW fruit and vegetable growers who sell their produce through the Melbourne Markets have against Victorian producers. It is the view of NSW Farmers that increasing access to minor uses of crop protection products for these farmers should be considered an enabler for growing the volume and value of horticultural production in NSW. As reported by consultants to a COAG Harmonisation of Control of Use project undertaken in 2011, the Victorian experience has not resulted in the materialisation of any additional risk to workers, the environment or consumers.

Minor use of chemicals is not appropriate in all industries, and gaps in chemistry can lead to decreased productivity and incentivise off-label use. Improved timeframes for product registration at a national level through the APVMA would likely result in a reduced demand on minor use products and improve access to new chemistry.

⁹ Rural Regional Affairs and Transport Committee estimates hearing, 23 May 2018, Canberra

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The need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products

NSW Farmers promotes the rights of farmers to use agricultural and veterinary chemicals provided they are used in accordance with label directions and industry best practice, and that they are used in a manner that recognises responsibility towards neighbours, the environment, consumers, employees and themselves. We continue to promote best practice in regard to farm chemical use in all industries, including the voluntary acceptance by them of appropriate quality assurance systems, and accept that industry best practices should be specific to the operations of, and risk posed by, those industries.

Farmers rely on innovation and investment from manufacturers to increase productivity and sustainability. As mentioned previously, review and reassessment drives uncertainty, and could reduce the willingness of manufacturers to invest in the Australian market. It is also critical that the APVMA's assessment processes are carried out in a timely manner so that products can be effectively incorporated into business management, including integrated pest management strategies, and that there is certainty in access to these products.

NSW Farmers supports the principle of industry self-regulation, except where an industry fails to self-regulate its operations and threaten the community, the environment, or other industries. There are situations where regulatory intervention is appropriate and necessary, provided it is carried out in conjunction with affected stakeholders (e.g. changes to 2,4-D label instructions to reduce spray drift incidence). Industry engagement with the APVMA is appropriate to ground-test the agency's work, but we do not consider that the APVMA's decisions are unduly influenced by this engagement – arguably, ensuring proper understanding of APVMA labelling is essential to ensure safe chemical use. The APVMA works with industry to ensure improvement and protections are safe for the public, and that label recommendations are relevant and protect the market reputation of Australian agricultural exports.

It is important that farmers retain access to critical chemicals that have been assessed and approved for use by the APVMA. Herbicides such as glyphosate have enabled many farmers in NSW to preserve soil health and stored carbon through no-till practices, as well as reducing chemical use in genetically modified canola systems. As per a study on the effects of a global restriction on glyphosate use:

There would be an annual environmental loss associated with a net increase in the use of herbicides of 8.2 million kg of herbicide active ingredient (+1.7%), and a larger net negative environmental impact, as measured by the environmental impact quotient indicator of a 12.4%. Also, there would be additional carbon emissions arising from increased fuel usage

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and decreased soil carbon sequestration, equal to the equivalent of adding 11.77 million cars to the roads.¹⁰

Chemical use should be seen as one element of a wider farming system that delivers environmental and production benefits. While we do not want to see the APVMA's scientific rigour diluted, NSW Farmers believes that the APVMA regulatory review and approvals should include consideration of impacts of regulatory decisions on the whole farming and environmental system including the use of other chemicals, alternative methods of control, herbicide resistance management, and the impacts of the control of weeds, pests and diseases.

The impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner

NSW Farmers' position on the relocation of the APVMA is no different to the majority of other agricultural stakeholders; we have consistently stated that relocation must not further reduce the agency's performance by causing additional delays to chemical reviews. At the time that the Australian Government announced the relocation of the APVMA to Armidale, NSW Farmers raised concerns about impacts on agency performance. In June 2016, National Farmers' Federation members voted against the relocation of the APVMA, with a statement issued after the meeting saying:

Many of the 170 staff at the APVMA are highly technical, specialist regulatory scientists whose expertise cannot be easily replaced if they choose to accept a redundancy package. This loss of capacity could add years to approval timeframes which are already failing to meet statutory requirements. The farm sector has a lot to lose if new chemical technologies are stuck in the approval process and can't get to market. The approval pathway is already a disincentive to registrants and Australian farms need equal access to technologies used overseas to compete. While we support the concept of decentralisation and supporting jobs in our regions, our main objective has to be improving agricultural productivity. We can't afford policies which put productivity second to political objectives.

It is difficult to link performance to the relocation, especially in the early stages, but NSW Farmers remains concerned about the timeliness of assessments. We note that applications assessed on time for the April-June quarter 2018 had increased to 85 per cent, but that the number of applications was considerably less than in other quarters. Assessment performance in 2016-17 was well below the target of 100 per cent.¹¹ The Independent Review of Performance noted that the agency has rarely met its assessment performance indicators.¹² Poor performance against these indicators is inherent within the APVMA, regardless of its location.

NSW Farmers suggests that it is more important to determine the root cause of this performance beyond delays caused by relocation and loss of key staff; it is more likely that consistent failure to

¹⁰ Graham Brookes, Farzad Taheripour & Wallace E. Tyner (2017) The contribution of glyphosate to agriculture and potential impact of restrictions on use at the global level, *GM Crops & Food*, 8:4, 216-228

¹¹ <https://apvma.gov.au/sites/default/files/docs/apvma-2016-17-portfolio-budget-statements.pdf>

¹² https://apvma.gov.au/sites/default/files/publication/28811-final_apvma_report_20171222.pdf

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meet targets is a sign that the performance indicators poorly reflect the time needed for chemical review and assessment within the APVMA's current operating budget. Increased pressure to complete reviews against current indicators could reduce the quality of the APVMA's assessment and erode community and industry trust.

Relocation of the APVMA to Armidale was not a move that was supported by NSW Farmers. However, it is now too far down the track to suspend or cancel the relocation without significant further disruption to the agency and industry. The relocation must be carefully implemented to balance assessment timeframes, health and safety, and staff workloads. We support the statement made by the APVMA CEO at the most recent Senate Estimates:

Exercising the flexibility inherent in the Armidale business operating model will support the APVMA to continue to implement the Government Policy Order by relocating operations, while maintaining our current and future regulatory performance, which protects the health and safety of Australians – and we will not lose sight of this through the relocation.¹³

Delivering on this statement will be integral to maintaining community and industry trust in the APVMA. We believe that retaining a small presence in Canberra is appropriate for any government agency, particularly one that interacts so frequently with other departments including the Canberra-based Department of Agriculture and Water Resources. It is also essential to retain the knowledge of experienced specialist staff that have made a personal decision not to relocate to the Armidale office.

RECOMMENDATION: That the APVMA maintains satellite presence in Canberra to retain essential scientific capacity and manage relationships with key stakeholders.

Conclusion



NSW Farmers members have told us that they hold the APVMA in high regard for its independence and scientific rigour. While we have ongoing concerns about the agency's performance and ability to meet timeframes, we are comfortable with its ability to make independent decisions about the safety of agricultural chemicals and veterinary medicines. NSW Farmers believes it is critical that the APVMA is adequately funded to both carry out its statutory obligations and to be able to implement recommendations from the Independent Review of Performance.

As an agency, the APVMA has faced significant disruption over the past few years; however, we do not believe this has had any negative impact on its ability to protect the community and industry without undue influence.

¹³ <https://apvma.gov.au/node/33456>



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