



Australian Government

Australian Government response to the Rural and Regional Affairs and Transport References Committee inquiry report: Independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

April 2019

INTRODUCTION

On 16 October 2018, the Senate referred the following matters to the Rural and Regional Affairs and Transport References Committee for inquiry and report by 1 February 2019:

The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA), with particular reference to:

- (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
- (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
- (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
- (d) the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products
- (e) the impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner
- (f) any other related matters.¹

The committee reported on this matter on 1 February 2019 and made nine recommendations, the Coalition Senators' dissenting report made no recommendations and the Australian Greens' dissenting report made two recommendations. The Australian Government provides the following response.

¹ *Journals of the Senate*, No. 123, 16 October 2018, p. 3927.

DETAILED RESPONSE TO THE RECOMMENDATIONS OF THE COMMITTEE REPORT

RECOMMENDATION 1

6.21 The Committee recommends that the Australian Government undertakes a comprehensive scoping study on the need for regulatory scientists across Australian Government agencies. The scoping study should consider:

- (a) the current educational, training and work experience environment for regulatory scientists
- (b) the likely future demand for regulatory scientists and the skills and competencies they will require
- (c) the findings of the Environmental Health Standing Committee (enHealth) on the need for regulatory scientists.

6.22 In undertaking this study, relevant educational and training bodies, and Australian Government agencies, should be consulted as required.

The Australian Government notes the recommendation.

The Department of Health's regulatory policy area is leading the Australian Government's engagement in enHealth's assessment of Australia's regulatory science workforce needs. The work of enHealth is ongoing; however, the outcomes are likely to address the intent of this recommendation.

RECOMMENDATION 2

6.23 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority works closely with the Australian education sector to identify and expand integrated learning opportunities that would provide science graduates with experience in regulatory environments.

The Australian Government notes the recommendation.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has been working closely with the University of New England (UNE), and in February 2017, the UNE began offering a Graduate Certificate in Science (Regulatory Science) and a Graduate Diploma in Science (Regulatory Science). A Master of Regulatory Science is also in development.

The government will consider the need to provide science graduates with additional opportunities for experience in regulatory environments in the context of the ongoing work from enHealth's assessment of Australia's regulatory science workforce needs.

RECOMMENDATION 3

6.29 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority progresses, as a matter of priority, the development and implementation of a robust quality control framework and a fit for purpose workflow management system.

The Australian Government notes the recommendation.

The government confirms that the APVMA is already progressing a robust quality management system that aligns with international best practices. The Learning and Development and Knowledge Management work is well advanced, and is a key component of the quality management system.

For registration activities, a workflow management system exists through the APVMA's current online portal and further improvements are expected as the digital strategy is implemented.

RECOMMENDATION 4

6.30 The Committee recommends that the Australian Government takes into consideration the disruption caused by the forced relocation of the Australian Pesticides and Veterinary Medicines Authority (including the ongoing impact on staff capability and capacity), and prioritises a fit-for-purpose and stable workforce over any decentralisation policy.

The Australian Government does not support the recommendation.

The Decentralisation Agenda forms part of the government's commitment to promote economic activity in the regions to ensure all of Australia benefits from our growing economy and employment opportunities. Decentralisation of public sector jobs outside of Canberra, inner Sydney and inner Melbourne prioritises the availability of stable, high quality government jobs and related business opportunities for regional people and economies.

A greater Australian Public Service (APS) presence in regional Australia brings government closer to the people it serves. The benefits go beyond service delivery. Closer proximity to rural and regional communities and stakeholders supports greater understanding of the views, needs and experiences of people living in regional Australia. It reinforces the government's strong connection with communities and the land.

A key focus for the Decentralisation Agenda is on ensuring relocations are rolled out in a sensible and methodical manner to minimise disruption and uncertainty for affected staff and stakeholders. All decentralisation decisions involve a detailed assessment of necessary funding management arrangements; potential costs and benefits, including economic and financial impacts; implementation planning; the results of any consultation; and the entity's capability to successfully deliver a transition to the location.

RECOMMENDATION 5

6.39 The Committee recommends that the Australian Government confirms its ongoing support for the Improved Access to Agricultural and Veterinary Chemicals Initiative and provides sufficient funding for the initiative over the forward estimates to ensure its continued operation.

The Australian Government notes the recommendation.

The government has committed \$14.3 million over six years (from 2014–15 to 2019–20) to the Improved Access to Agricultural and Veterinary Chemicals initiative, the aim of which is to increase the number of safe, appropriate and efficacious uses of new and existing agvet chemical products available in the Australian market.

The initiative has provided 149 grants totalling \$7.9 million, to fund applications for chemical uses, through either a permit, or inclusion on a registered product's label. The program has already delivered 31 new permits and two additional uses on existing product labels, providing improved access for Australian producers. The government expects the benefits of improved access to chemicals for Australian agriculture to continue to accrue as projects are completed.

The program has also funded the development of an Australian crop group list, which identifies use patterns that can apply to multiple crops with little or no need for extra data. Additionally, the APVMA is identifying those uses currently approved under permit that would be suitable to transfer to a product label.

The government will consider the need for additional or ongoing funding as and when required.

RECOMMENDATION 6

6.40 The Committee recommends that the Australian Government commissions an independent assessment of the impact of regulatory costs on the registration of minor use chemicals, with a view to obtaining evidence that would inform policy and consider the availability of minor use chemicals in Australia.

The Australian Government notes the recommendation.

In agriculture ‘minor use’ is accepted to mean a use of a product that would not produce sufficient economic return to an applicant for the registration of the product to meet the cost of registering the use. Australia is a small sector of the global chemical market. The barriers to registering chemicals for a minor use (small use) in Australia (small market) are well understood.

The government has taken significant steps to reduce the regulatory costs associated with Australian producers accessing chemicals for minor uses. A permit issued by the APVMA allowing a minor use is \$350. A permit has equivalent rigor of assessment as a registration and meets the same regulatory tests. In issuing a permit for a minor use the APVMA will, if necessary, set a maximum residue limit allowing treated produce to be lawfully supplied.

As part of the government’s \$14.3 million commitment to improving chemical access for agricultural and veterinary chemicals, \$7.9 million has been allocated in grants to rural research and development corporations. These grants contribute, in part or in full, toward the costs associated with data to support applications to the APVMA for minor uses. The government has also supported the APVMA to establish crop group and related guidance, which identify use patterns that can apply to multiple crops with little or no need for extra data.

Additionally the government continues to work with our partners in the National Registration Scheme for Agricultural and Veterinary Chemicals to harmonise control of use arrangements. A significant component of harmonisation to date has been the ability, in some cases, for a producer to treat a different pest in a crop than the pest stated on the APVMA approved label. This reduces the regulatory costs associated with farmer access to minor uses.

RECOMMENDATION 7

6.50 The Committee recommends that the Australian Pesticides and Veterinary Medicines Authority consults with key stakeholders to establish a formal mechanism for ongoing liaison and discussion. The forum should develop clear terms of reference which set out its working arrangements, and the minutes of each meeting should be recorded and made public in a timely manner.

The Australian Government notes the recommendation.

The proposed government amendments to the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 include establishing a governance board for the APVMA, with a formal mechanism for establishing industry committees. This would provide for ongoing discussions between industry and the APVMA. Currently the APVMA regularly meets with key stakeholders on a range of different issues. The governance board’s committees would provide for a more formal process.

RECOMMENDATION 8

6.65 The Committee recommends that the Australian Government develops and implements a national strategic plan for agricultural and veterinary pest-control innovation, which addresses Australian specific environmental conditions and pests.

The Australian Government notes the recommendation.

The government actively participates in strategies to address pests of national significance including: the Australian Pest Animal Strategy 2017-2027; the Australian Weeds Strategy 2017–2027; the National Wild Dog Action Plan; and the RHD Boost plan – a national project to boost existing biological controls of pest rabbits including by releasing a naturally-occurring Korean-variant strain of rabbit calicivirus called RHDV1 K5.

The government has committed more than \$12 million towards research and development projects for new and improved tools and technologies that control established pest animals and weeds. This is part of a wider allocation of \$50 million over four years to 2018–19 to improve the tools, technologies, information and skills farmers and their communities need to tackle pest animals and weeds.

RECOMMENDATION 9

6.76 The Committee recommends that the Department of Agriculture and Water Resources and the Australian Pesticides and Veterinary Medicines Authority undertake a formal study of the United Kingdom Pesticides Forum and the United States Environmental Protection Agency Pesticide Program Dialogue Committee with the aim of establishing a similar forum for the Australian regulatory environment.

The Australian Government notes the recommendation.

The Department of Agriculture and Water Resources and the APVMA will consider the various collaborative forums used by other regulatory agencies (including the United Kingdom Pesticides Forum and the United States Environmental Protection Agency Pesticide Program Dialogue Committee) to improve engagement and enhance the dialogue about chemical registration with the wider Australian community.

DETAILED RESPONSE TO THE AUSTRALIAN GREENS' DISSENTING REPORT

RECOMMENDATION 1

That the Commonwealth Government order the conduct of a full and independent review of the chemical risk of glyphosate immediately.

The Australian Government does not support the recommendation.

The objective scientific facts show that glyphosate-based products are safe when used in accordance with label instructions. Multiple international agricultural chemical regulators, including those from the United States of America; Canada; Germany; New Zealand; and the European Union, as well as the United Nations' Food and Agriculture Organization and the World Health Organization have all separately assessed glyphosate and have concluded it is safe to use.

In 2016, the APVMA evaluated a range of contemporary scientific information about glyphosate and concluded that its use in accordance with the label instructions in Australia does not pose a cancer risk to humans and is unlikely to have harmful effects on human beings or the environment. The report of the APVMA's review is available at www.apvma.gov.au/node/13891.

It would be inappropriate for the government to direct the APVMA to perform any regulatory activity that contradicts its science-based decision-making. To do so would be incompatible with the authority's status as independent of government and its commitment to evidence led, risk-based decisions in regulating agvet chemicals in Australia.

RECOMMENDATION 2

That the Government introduce legislation to reinstate the APVMA re-approval and re-registration scheme that was repealed in 2014.

The Australian Government does not support the recommendation.

The government is committed to ensuring that the agvet chemicals available to Australian producers and the community are safe for humans, animals and the environment.

The re-approval and re-registration scheme, unlike its international namesakes, would not, in and of itself, cause the removal or withdrawal of an active constituent or chemical product from the Australian market. Rather it sought, through an administrative process, to identify and direct active constituents and chemical products in to the existing APVMA chemical reconsideration scheme. Consequently, it was arbitrary and duplicative, placing additional burden on the APVMA and the chemicals industry, without materially improving chemical safety for Australians.

The APVMA already has the discretion to act promptly to reconsider any active constituent or chemical product in light of new evidence, as and when it becomes available. Based on the nature of the new evidence, it can review the chemical against all the statutory criteria, or only those that it considers relevant to the new information. By avoiding locking the APVMA into an arbitrary system of timed reviews that have no regard for the relative risk that a chemical poses to the public, it can direct its regulatory resources at those chemicals that are most likely to be of concern.

