Chapter 6

Committee view and recommendations

6.1 The APVMA has a crucial role in assessing, registering and regulating agvet chemicals in Australia. An effective and efficient regulator is essential to protect the health and safety of people, animals and the environment, and to support trade and commerce in agricultural commodities. To carry out its legislated functions, the APVMA must make efficient decisions to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products, whilst at the same time maintaining the confidence of both industry and the community.

6.2 A number of issues have combined to create a situation where the APVMA will face significant challenges in maintaining its ability to effectively regulate agvet chemicals. The decision to relocate the APVMA to Armidale has hampered the regulator's ability to address a number of long-running issues with regard to its performance and funding. Without any prior strategic planning to address the inevitable upheaval that would come from relocating a specialist scientific agency, the regulator has lost important institutional knowledge and technical expertise and must now overcome numerous challenges to effectively and efficiently carry out its functions.

6.3 Evidence to the Committee has suggested that it will take the APVMA a number of years to regain its lost scientific, technical and management strength. The concern was raised that this will not only affect the APVMA's ability to effectively regulate agvet chemicals, but will also hinder the implementation of urgent organisational reforms required for its effective operation.

Consequences of relocation

6.4 The Committee is concerned about the manner in which the APVMA was relocated to Armidale and of its impact on the availability of staff expertise and assessment timeframes. It notes the flow-on effects for farmers across Australia who require timely and certain access to pesticides and veterinary medicines. Further, the relocation has the potential to undermine, or at least set back, the benefits that were to have come from reforms within the authority.

6.5 The Committee was informed that the satellite office in Canberra was retained in order for the APVMA to maintain its performance and fulfil its statutory responsibilities. Despite the best efforts of the APVMA in exploring a range of mechanisms to fulfil these functions from Armidale, including that of drawing on the private sector, the APVMA had no other option than to retain a satellite office in Canberra.

6.6 Whilst the Committee appreciates the rationale for retaining a Canberra satellite office, the evidence is clear that the relocation of the APVMA to Armidale has undermined the authority's ability to retain scientific and other experienced staff that would allow it to undertake its regulatory functions in a timely manner.

6.7 The Committee notes that staff shortages have resulted in management-level staff undertaking non-registration-related activities, with increasing amounts of time being spent on general application processing at the expense of other activities. That the APVMA is currently reviewing several aspects of its own operations, and is the subject of proposed legislative change, adds to the non-regulation-related workload of the authority.

6.8 The Committee regrets that the relocation has also brought into question the independence of the authority and has delayed the implementation of essential reforms within the authority, which would have improved its performance as well as public confidence in its operations.

6.9 The Committee believes the importance of having a regulator that is able to conduct robust, scientifically based regulatory activities cannot be underestimated and should not be jeopardised.

6.10 It is vital that the regulator maintains the necessary expertise to assess all applications it receives, and is able to oversight and control the assessment process. The Committee upholds the view that sufficient staff should be retained so as to ensure the authority is able to fulfil its regulatory responsibilities in a timely and efficient manner. The Committee also appreciates the considerable efforts underway by the APVMA to attract and secure staff, and in particular regulatory scientists.

Use of international data to improve regulator efficiency

6.11 The Committee heard suggestions that within a risk-based framework, a greater use of international data and assessments would improve the regulator's efficiency.

6.12 The Committee welcomes the direction issued by APVMA CEO, Dr Parker, to APVMA staff detailing expectations with regard to the use of international data, standards and assessments. Whilst the Committee is of the view that the APVMA must make decisions based on Australian legislative requirements, the regulator should incorporate the findings of international assessments as appropriate.

6.13 The Committee notes that whilst the authority has made significant effort in the area, some industry stakeholders remain concerned about the APVMA's processes for accepting international data in support of registering products in Australia. The Committee therefore encourages the APVMA to continue to liaise with industry to provide clarity to applicants.[1]

Training regulatory scientists

6.14 The Committee recognises the particular specialist skills required by regulatory scientists and the difficulties the APVMA faces in recruiting and training

1 See: Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 2; Australian Pesticides and Veterinary Medicines Authority, *Guidance for Applicants—Submission of International Data, Standards and Assessments*, https://apvma.gov.au/node/14186 (accessed 4 January 2019).

new scientific staff, which itself can take three to five years. The reported global shortage of regulatory scientists adds a complicating factor.

6.15 The Committee acknowledges the work of the APVMA to train its newly recruited regulatory scientists through the Accelerated Regulatory Science Training Program. However, it believes a 10-month training program, however intensive, cannot compensate for the lost experience and expertise that was caused by the decision to relocate the authority.

6.16 Having considered the evidence presented, the Committee believes that over the next five years, there is a risk that the quality of the authority's assessments will be affected by a lack of expertise and experience. The absence of a robust quality control framework exacerbates this problem.

6.17 Having regard to evidence of a shortage of regulatory scientists, and the need for regulatory scientists across a number of government agencies, the Committee believes there is merit in investigating the education, training, and future supply of regulatory scientists in Australia. The Committee is of the view the sector would benefit from the establishment of more graduate courses in regulatory science, and consideration of a dedicated school of regulatory science.

6.18 The Committee acknowledges the current work being undertaken by enHealth in relation to the regulatory science workforce (both in the private and public sector), and encourages the APVMA to continue its participation in this study. The Committee considers, however, that the Australian Government should be treating this issue as a matter of priority.

6.19 The Committee also believes there is much to be gained from the regulator working with existing educational institutions to provide practical experience for science students in a regulatory environment, with the long-term outcome of ensuring Australian agencies are able to attract suitably qualified staff.

6.20 In light of these views, the Committee makes the following recommendations for a scoping study on the Government's need for regulatory scientists, and the expansion of integrated learning opportunities in regulatory environments for science graduates.

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; and**
- **(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.

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.

Regulator performance and efficiency

6.24 The Committee acknowledges there is a longer history of performance and efficiency concerns in relation to the APVMA, and that the regulator has been subject to significant administrative, legislative and regulatory change.

6.25 The additional pressure created by the relocation to Armidale, not the least of which has been caused by the loss of a significant proportion of the regulator's experienced staff, has exacerbated a number of underlying problems. The relocation has caused considerable disruption to staff and severely weakened the authority's ability to operate effectively and efficiently. Based on the evidence before it, the Committee recognises that the Government must prioritise the authority's ability to perform its regulatory functions over imposing an overarching policy of decentralisation.

6.26 The Committee expresses concern that reforms such as a robust quality control framework and a fit-for-purpose workflow management system remain unfulfilled at a time of significant disruption. Indications from the regulator are that these reforms remain years from completion.[2]

2 The implementation of the authority's digital strategy was funded over three years from mid-2018; and the internal quality framework remains in the planning stages and will not be implemented until after the regulator's relocation to Armidale has been completed. Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 5, 23, 53; Australian Pesticides and Veterinary Medicines Authority, *Digital Strategy 2018–2022*, p. 17.

6.27 The absence of these measures has the potential to affect the quality and efficiency of the regulator's work, endanger its ability to fulfil legislative requirements, and undermine trust in the authority.

6.28 The Committee therefore recommends that the APVMA progresses, as a matter of priority, a robust quality control framework and a fit-for-purpose workflow management system.

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.

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.

APVMA funding model and its implications

APVMA cost recovery funding model

6.31 The Committee shares the concern of a number of submitters that the APVMA is not operating on a sound financial footing, particularly at a time of organisational upheaval, and encourages the timely completion and implementation of the current funding review.

6.32 The Committee does appreciate the challenge, as highlighted by Dr Parker, of ensuring sufficient staff expertise remains within the APVMA to carry out the authority's regulatory functions upon which the cost recovery funding model is dependent. The departure of staff has impacted on productivity and will continue to do so.

6.33 Notwithstanding this point, the Committee believes the cost recovery funding model is comparable to the funding models of other national and international regulators.

Access to chemicals and veterinary medicines in Australia

6.34 The Committee acknowledges that the combination of small market size and regulatory cost has an impact on access to agvet chemicals for minor uses in Australia. That applications for registration contain fewer label usages has negative consequences for farmers in general, and for those who farm specialty crops or animals in particular.

6.35 The APVMA's new cost recovery implementation statement, scheduled for release in 2019–20, may result in increases in some costs. In light of this, some submitters suggested that a reduction in fees for the registration of minor use

chemicals would provide a way to compensate for the low commercial return on investment.

6.36 The Committee recognises the Government's efforts to address the problem of access to minor-use chemicals through the Improved Access to Agricultural and Veterinary Chemicals Initiative, which provided some funding for the registration of agricultural chemical products for minor uses and specialty crops. However, the Committee also recognises that the allocated $8 million of funding was committed for 2014–2018. The Committee takes the view that funding for this initiative should be continued.

6.37 The Committee recognises that a thorough assessment of the actual impact of regulatory costs on the registration of chemicals for minor uses is necessary to inform policymaking into the future. Understanding the impact will allow for effective and targeted policymaking to address chemical availability in Australia.

6.38 Accordingly, the Committee makes recommendations with regard to funding the Improved Access to Agricultural and Veterinary Chemicals Initiative, and to assessing the impact of regulatory costs on the registration of minor use chemicals in Australia.

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.

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.

Perceptions of independence

6.41 The Committee received significant evidence with regard to the cost recovery funding model and its relationship to the perceived independence of the regulator.

6.42 Regardless of whether the authority does recover the full cost of its activities, because the regulator is funded by those whose products it regulates, its cost recovery funding arrangement is perceived by some as a conflict of interest. This funding model, however, is not a unique arrangement for regulatory agencies in Australia or internationally; and it complies with the Australian Government Charging Framework.

6.43 The Committee is confident that the authority's clearly legislated regulatory responsibilities do not allow for industry to unduly influence the decisions of the regulator, by the fact that it is industry funded. Furthermore, the Committee does not share the view, held by some submitters, that the APVMA has an incentive to approve chemicals to gain funding through levies or that companies might be encouraged by the APVMA to create products for their registration so the APVMA can meet funding targets and increase capital.

6.44 The Committee agrees with those who argue that the current funding model provides adequate checks and balances to prevent preferential treatment, such as the acceleration of any particular chemical application from any particular manufacturer.

6.45 The Committee considers the current funding arrangement to be adequate and appropriate. Further, it believes application fees provide an incentive for the submission of quality applications.

6.46 The Committee acknowledges the industry is united in the view that the funding model does not allow for undue influence over the decisions of the regulator, which are robust and based on sound scientific principles. The Committee does see value, though, in looking to formalise some of the contact between the regulator and industry so as to discuss, in a transparent manner, a range of issues with regard to agvet chemical regulation in Australia.

Liaison between industry and the APVMA

6.47 The Committee accepts that it is important the APVMA has direct contact with industry groups and applicants, and responds to broad industry concerns. While the Committee acknowledges the efforts of the APVMA to make assessment requirements clear to applicants, there is considerable scope for a more formalised and ongoing engagement.

6.48 The Committee recognises merit in re-establishing an industry advisory committee or establishing a similar liaison forum. The purpose of the communication mechanism would be to discuss the needs of those who use and rely upon the APVMA's services. While it is not the role of the Committee to prescribe the nature and form of any such forum, as this is a matter for the APVMA and involved industry stakeholders to develop, consideration should be given to ensure that there are adequate opportunities to discuss specific issues, for instance plant, pests or veterinary medicines. Furthermore, any such forum should provide for broad, representative membership and develop clear terms of reference which set out the working arrangements. To provide for greater transparency, the minutes of meetings of the liaison forum or committees should be recorded and published in a timely manner.

6.49 The Committee therefore recommends that the APVMA, in cooperation with industry, develop a liaison committee or forum to facilitate open and transparent communication between industry and the APVMA.

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.

Chemical reconsideration

APVMA's process for chemical reconsideration

6.51 The Committee acknowledges the significant concern expressed by some submitters as to the APVMA's process and schedule for the review of agvet

chemicals, some of which were grandfathered into the NRS, having been assessed under previous standards.

6.52 The Committee received evidence of the APVMA's Chemical Review Program and examined its chemical risk process, which combines hazard and exposure assessments through a weight-of-evidence approach.

6.53 As to the timing of reviews, the Committee acknowledges the diverse views with regard to risk-based versus scheduled review of agvet chemicals. The Committee supports the APVMA's current risk-based approach to chemical reconsideration, believing it strikes an appropriate balance between community safety and access to chemicals. This approach allows the regulator to reconsider a chemical whenever it identifies evidence that would support reconsideration.

6.54 The Committee is concerned, however, about the delay in the current schedule of reconsiderations and encourages the APVMA to ensure sufficient resourcing is dedicated to this task.

Reconsideration of glyphosate, and its use in Australia

6.55 The Committee considered the approach taken by the APVMA in its reconsideration of glyphosate following the IARC classification of the chemical as 'probably carcinogenic to humans'.

6.56 The Committee acknowledges the range of strongly-held views about the APVMA's decision on glyphosate. However, it considers the APVMA's scientific processes to be robust, noting that all 264 of the studies referenced in the IARC report were independently evaluated by the OCS, in addition to other studies and data.

6.57 Further, the Committee was informed that the regulator did not receive any new scientific evidence during the consultation period relating to the possible carcinogenicity of glyphosate that it had not already considered.

6.58 The Committee points out that many of the concerns raised about the APVMA assessment are addressed in the APVMA's *Final Regulatory Position* report on glyphosate and in other APVMA material about the decision.

6.59 The Committee recognises the centrality of glyphosate to the sustainability and productivity of Australian farming. It is concerned, however, that neither the government nor industry has contemplated a loss of access to glyphosate or the impact in Australia of a ban on glyphosate overseas.

6.60 While the Committee does not hold a view on alternative methods of pest control to glyphosate, it recognises the need to consider alternative techniques and methods that can be used to manage pests when glyphosate is not accessible. However, the Committee also appreciates that concerns regarding viable alternatives to glyphosate stem from a broader problem of limited investment in innovation and research.

Chemical innovation

6.61 The Committee was very concerned by evidence that international chemical companies are reluctant to contribute resources towards research, development and

innovation to address Australian-specific pests and circumstances, particularly at a time of growing pest resistance. The Committee appreciates that Australia's small market has placed it at a competitive disadvantage globally and that research and development to discover new products is an expensive undertaking.

6.62 Nevertheless, the Committee is of the view the lack of research and development for Australian-specific conditions—whether for chemicals or other weed control strategies—has the potential to endanger the productivity and sustainability of Australia's agricultural industries.

6.63 The Committee supports the innovative programs run by the GRDC and other research organisations, to develop pest solutions for Australian-specific conditions. However, it believes these programs are not sufficient to address the current situation.

6.64 The Committee is of the view that the Australian Government cannot wait for clear market failure or the development of uncontrollable pests before taking stronger action. Accordingly, the Committee recommends the development of a coordinated national approach to agvet innovation, by way of a national strategic plan. The plan should be underpinned by an audit of areas where alternative chemicals or practices are not available to the Australian market and an evaluation of existing and developing pesticide and herbicide resistance. The Committee further suggests that sufficient funding be made available to implement the strategic plan.

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.

Transparency and community confidence

6.66 Whilst stakeholders with active and regular engagement with the APVMA spoke of their confidence in the regulator's scientific rigour, others questioned its impartiality, processes and evaluations. The Committee recognises there are concerns in some areas about the quality of decisions made by the regulator, particularly from organisations and individuals who do not have direct or regular contact with the authority.

6.67 The Committee heard concerns about a potential conflict in the role of the APVMA to protect the community, promote ecologically sound development, and further trade. It considered evidence that a product-specific focus to assessments failed to take into consideration cumulative exposure to agvet chemicals and that regulatory science was not sufficiently precautionary. The Committee also considered concerns raised during the inquiry that the evidence upon which the APVMA relies to make assessments is not publicly available for peer review; and that the APVMA did not consult the community.

6.68 The Committee recognises the concerns expressed by a number of stakeholders about the APVMA's processes. The Committee did not receive evidence that would lead it at this time to question the scientific basis of the regulator's assessments. The Committee believes the APVMA, through its regulatory approach to

the evaluation of data, balances the need to ensure community safety whilst also supporting the viability of Australian agriculture. The Committee received several examples of the APVMA's independence in the face of strong industry resistance and of the APVMA's efforts to promote transparency by regularly publishing material, including its decisions.

6.69 Nevertheless, the Committee believes that the industry and the regulator both need to consider the industry's social licence to operate—not in terms of compromising the scientific basis of the decisions made by the regulator, but in communicating more effectively with the community about decisions, processes and procedures.

6.70 The Committee acknowledges the reservations some stakeholders have expressed about the responsiveness of the APVMA to community concerns and the absence of general community consultation processes. It is concerning to hear of the lack of confidence some in the community have in the scientific basis of the regulator's decisions.

6.71 The Committee notes the authority has no proactive means to engage with consumers and others concerned about its procedures and assessments. This absence of engagement can lead to a perception that the regulator's assessments are flawed, despite the regulator's international reputation for robust, scientifically-based assessments.

6.72 As detailed in this report, there are other regulators that have established robust, community-focused communication mechanisms. The Committee encourages the APVMA to draw on the experience of these regulators, in particular the UK Pesticides Forum and the United States EPA Pesticide Program Dialogue Committee (PPDC) and develop its own communication mechanism accordingly.

6.73 Drawing upon the cases of other regulators, the Committee believes there would be much benefit in the establishment of a pesticides forum, based on the UK or PPDC model that would bring stakeholders from all sectors together to discuss issues of mutual concern and to express these concerns to the appropriate government agencies.

6.74 The Committee believes an appropriately constituted forum could go some way to allowing the APVMA to communicate its complex processes and procedures more effectively. It would also enable the regulator to detail the extent of its scientific assessment of applications, including supporting data. Furthermore, through such a forum, the APVMA and industry could more directly address community concerns. Conversely, such a forum would permit the public to question the APVMA, to raise concerns and develop a more informed understanding of the APVMA's regulation.

6.75 The Committee therefore recommends that a study of the UK Pesticides Forum and the EPA's PPDC be undertaken with a view to establishing a similar forum in Australia. The forum should have established aims, terms of reference, and objectives; include diverse and representative membership; make publically available its discussions and deliberations; and have its operating costs funded by government.

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.

Senator Glenn Sterle

Chair