

# Chapter 3

## The APVMA charging framework

3.1 The APVMA is funded largely through fees, levies and charges imposed on registrants on a cost recovery basis. However, the sustainability of the current model in providing sufficient resources for the authority was questioned during the inquiry.

3.2 Although this type of funding model is used by other regulatory agencies in Australia and around the world, there were differing opinions as to whether a cost recovery model could lead to actual, or perceived, undue influence on the decisions of the regulator.

3.3 While many stakeholders recognised the cost recovery model as appropriate, some expressed concern that certain fees could act as an impediment to registering certain chemicals, particularly those for minor uses. This situation was made more complex to resolve by the small size of the Australian market.

3.4 This chapter considers the APVMA's charging framework and explores the views of submitters in relation to it.

### History of the government charging framework

3.5 A 2001 Productivity Commission review of Commonwealth cost recovery arrangements found almost all Australian government agencies recovered some of their costs, and that the proportion was increasing. At that time, more than \$3 billion was raised annually by agencies through cost recovery. The review recommended that the Government adopt a formal cost recovery policy for agencies undertaking regulatory and information activities.<sup>1</sup>

3.6 In December 2005, the Australian Government established a formal cost recovery policy, administered by the Department of Finance and Deregulation. The central principal of the policy was that:

Agencies should set charges to recover all the costs of products or services where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group, and where charging is consistent with Australian Government policy objectives.<sup>2</sup>

3.7 In April 2015, the Australian Government agreed to implement a whole-of-government charging framework to apply across the general government sector. The framework consists of:

- a charging policy statement, providing the rationale for charging activities;

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1 Productivity Commission, *Cost recovery by Government Agencies*, No. 15, August 2001, pp. XXVIII, LIV.

2 Australian Pesticides and Veterinary Medicines Authority, *Cost Recovery Impact Statement: Covering the Period 1 July 2013 – 30 June 2015*, 2012, pp. 7–8.

- charging considerations to guide decision-making on appropriate charging; and
- charging principles to guide design, implementation and review of charging activities.<sup>3</sup>

3.8 The Australian Government charging policy states:

Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for it unless the Government has decided to fund that activity. Where appropriate for the Australian Government to participate in an activity, it should fully utilise and maintain public resources, through appropriate charging. The application of charging should not, however, adversely impact disadvantaged Australians.<sup>4</sup>

### Charging by other agencies

3.9 In addition to the APVMA, other regulatory agencies, including the TGA, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and FSANZ, charge registrants for the cost of evaluation and other regulatory services.<sup>5</sup>

3.10 The Committee received evidence that all comparable international regulators charge 'the regulated entity for access to [the] chemicals market in that country', though the exact charging mechanism varies. For instance, the Committee heard that in the United States the entire evaluation fee is charged up-front rather than being partly recovered through levies on sales.<sup>6</sup>

3.11 The New Zealand Government expects its Environmental Protection Authority to 'set fees that recover a fair and reasonable proportion of the costs' of providing its services. It is funded through a combination of fees and charges, and crown funding.<sup>7</sup> The New Zealand Ministry for Primary Industries similarly receives crown funding and revenue from levies and application fees.<sup>8</sup>

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3 Department of Finance, *Australian Government Charging Framework*, Resource Management Guide No. 302, July 2015, p. 4.

4 Department of Finance, *Australian Government Charging Framework*, Resource Management Guide No. 302, July 2015, p. 7.

5 Department of Agriculture and Water Resources, *Submission 9*, p. 4; Pastoralists & Graziers Association of Western Australia, *Submission 22*, p. 4.

6 Department of Agriculture and Water Resources, *Submission 9*, p. 4; CropLife Australia, *Submission 10*, p. 5; United States Environmental Protection Agency, *Submission 109*, p. 2; Dr Brian Richards, Executive Director, Office of Chemical Safety; Director, National Industrial Chemicals Notification and Assessment Scheme, *Committee Hansard*, 20 November 2018, p. 34.

7 New Zealand Environmental Protection Authority, *Annual Report for the Year Ended 30 June 2018*, pp. 26–31; New Zealand Environmental Protection Authority, *Fees, Charges and Cost Recovery*, <https://www.epa.govt.nz/applications-and-permits/fees-and-charges/> (accessed 3 January 2019).

8 New Zealand Ministry for Primary Industries, *Annual Report 2017–2018*, p. 78.

3.12 The Canadian PMRA charges fees for the review of applications to register pesticides, and an annual charge for every registered pesticide. It also receives government funding.<sup>9</sup> The Canadian Veterinary Drug Directorate, part of Health Canada's Health Products and Food Branch, similarly charges a number of fees including for evaluation, licencing and authority to sell.<sup>10</sup>

3.13 Before an active substance can be used in a plant protection product within the European Union, it must be approved by the European Commission following scientific and technical evaluation by a rapporteur member state. Most rapporteur member states charge a fee for the evaluation of a new active substance.<sup>11</sup> Countries within the European Union authorise plant protection products within their borders and ensure compliance with EU rules. Member states are permitted to cost recover through fees and charges. These vary between countries.<sup>12</sup>

### **APVMA funding**

3.14 The APVMA is funded through fees, levies and other charges imposed under legislation, with the exception of specific government-funded projects to improve or enhance the authority's ability to perform its legislated functions. The relocation to Armidale and reforms stemming from the 2015 white paper were funded by government.<sup>13</sup>

3.15 DAWR told the Committee that APVMA funding arrangements complied with the charging framework. The department also confirmed that the authority's regulatory activities were subject to the Australian Government Cost Recovery Guidelines, which establish the overarching framework for the design, implementation and review of regulatory charging activities.<sup>14</sup>

3.16 The APVMA's current cost recovery arrangements were implemented on 1 July 2013 for a period to 30 June 2015, during which time a first-principles review

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9 Government of Canada, *Pesticide Registration Cost Recovery*, <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/product-application/cost-recovery.html> (accessed 3 January 2019).

10 Government of Canada, *Fees for Veterinary Drugs*, <https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/veterinary-drugs.html> (accessed 3 January 2019).

11 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, p. 47; European Commission, *Approval of Active Substances: Application, Fees, Data*, [https://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/application\\_report\\_en](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/application_report_en) (accessed 3 January 2019).

12 Reason Group, *Independent Review of Assessment Performance: Report Australian Pesticides and Veterinary Medicines Authority*, December 2017, p. 47; European Commission, *Procedure to Apply for Authorisation of a PPP*, [https://ec.europa.eu/food/plant/pesticides/authorisation\\_of\\_ppp/application\\_procedure\\_en](https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure_en) (accessed 3 January 2019).

13 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 104.

14 Department of Agriculture and Water Resources, *Submission 9*, p. 4.

of the APVMA's cost recovery arrangements was to have been completed.<sup>15</sup> The 2013 cost changes were intended to address identified shortfalls in the authority's funding in preparation for a subsequent 2015 cost recovery impact statement. However, neither the first-principles review nor the 2015 cost recovery statement were completed within the established timeframe. The cost recovery statement is now scheduled for 2019–20 and the authority continues to operate on the cost recovery arrangements introduced in 2013.<sup>16</sup>

3.17 The authority incurs costs through registration assessments, renewals of existing product registrations, and by undertaking a variety of post-market compliance, monitoring and enforcement activities.<sup>17</sup>

3.18 The APVMA recovers the costs of registrations and approvals through application fees and levies. The costs of assessing an application are collected in two parts: 40 per cent of the assessment charge is recovered upfront through an application fee; the balance is recovered through a levy on the annual value of sales.<sup>18</sup>

3.19 The cost to assess an application for registration is split to ensure application fees are not a disincentive to bring new and innovative products to market. This is particularly the case for small businesses, niche products, and chemical products with low value of sales. It also aims to encourage competition and ensure equitable access to the chemicals market for the producers of generic variants.<sup>19</sup>

3.20 Post-market compliance activities conducted by the APVMA, including good manufacturing practice assessments, licencing, export certificates and other investigation and enforcement activities are subject to fees.<sup>20</sup>

3.21 The APVMA's fees, levies and charges are credited to a special appropriation, created under s. 58(6) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, held and managed by DAWR, for and on behalf of, the APVMA.<sup>21</sup>

3.22 The following table (Table 3.1) details the APVMA's income sources during 2017–2018, showing the breakdown and proportion of fees and levies.

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15 Australian Pesticides and Veterinary Medicines Authority, *Cost Recovery Impact Statement: Covering the Period 1 July 2013 – 30 June 2015*, 2012, p. 7.

16 Australian Pesticides and Veterinary Medicines Authority, *Cost Recovery Impact Statement: Covering the Period 1 July 2013 – 30 June 2015*, 2012, p. 52; Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 34.

17 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, pp. 3–4.

18 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 6.

19 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 6; Department of Agriculture and Water Resources, *Submission 9*, p. 4.

20 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, p. 6.

21 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 104.

**Table 3.1—APVMA income sources 2017–18**

<b>Income source</b>	<b>Income (\$'000)</b>	<b>%</b>
Receipts from industry		
<i>Levies</i>	18,802	47.97
<i>Application fees</i>	6,246	15.94
<i>Annual fees (renewal fees)</i>	5,604	14.30
<i>Other receipts from industry</i>	2,272	5.80
Parliamentary appropriation	6,056	15.45
Other revenue	215	0.54
<b>Total Income</b>	<b>39,195</b>	<b>100.00</b>

*APVMA Annual Report – total income 2017–18*<sup>22</sup>

3.23 DAWR explained to the Committee the benefits of a cost recovery arrangement, stating:

Cost recovery measures improve the transparency of the costs of sound management of chemicals and preserve the integrity of those management systems thereby ensuring they maintain adequate resourcing to protect human, animal and environmental health and Australia's interests as an agricultural exporter.<sup>23</sup>

3.24 An independent review of the APVMA's cost recovery arrangements in 2017 conducted by PWC did, however, raise some concerns about the sustainability of the authority's funding. PWC found that:

- the fees charged by the APVMA were not based on the workload of individual applications;
- there was no annual indexation of charges;
- the prices set were not consistent or reflective of the true costs of undertaking activities;
- revenue forecasts were optimistic and not representative of actual results; and
- budget allocations for the authority are aligned to a forecast activity level that may not have been achievable due to reduced volumes and decreased revenue.

22 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 78.

23 Department of Agriculture and Water Resources, *Submission 9*, p. 4.

In particular, the price structure for applications did not result in a sustained 40 per cent cost recovery.<sup>24</sup>

3.25 In terms of its financial position, the APVMA recorded a deficit for 2017–18 of \$880,000; and has run an operating loss since 2014–15. The authority's equity balance of \$6.418 million was more than \$500,000 below the targeted equity position of \$7 million, and lower than the 2016–17 total equity balance of \$6.798 million. The APVMA's target equity balance of \$7 million is equivalent to three months operating expenses, regarded as sufficient to cover periods of variations between revenue and expenses as a consequence of movement in activity volume. PWC noted a downward trend in the level of equity reserves at the end of reporting years once normalised for equity injections.<sup>25</sup>

3.26 The APVMA observed that the structure of payments affected the cash flow of the authority. The authority's primary income was derived from levy payments which come due in December and June; it also received registration payments in May and June—meaning the majority of revenue was paid at three points during the year. Although cash holdings could exceed \$7 million at points during the year, the authority had to operate to keep cash levels above \$2 million as an operating reserve to ensure sufficient cash was available to pay creditor expenses.<sup>26</sup>

3.27 DAWR acknowledged the APVMA's financial position was deteriorating and could not be sustained if expenditure and cost recovery pressures remained unaddressed.<sup>27</sup> However, the APVMA's *Annual Report 2017–18* indicated the planned 2019–20 cost recovery impact statement was expected to address some of these issues in the context of a new business operating model.<sup>28</sup>

3.28 DAWR informed the Committee that the APVMA was currently reassessing the entirety of its regulatory activities to ensure the fees and charges appropriately reflected the costs of the activities and the administrative infrastructure supporting them. The APVMA announced it would implement a renewed cost recovery implementation statement in 2019–20; with interim measures to retain positive cash flows.<sup>29</sup>

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24 PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, pp. 3–4, 7.

25 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 14, 80, 87; PricewaterhouseCoopers, *Australian Pesticides and Veterinary Medicines Authority: Review of Cost Recovery Arrangements*, October 2017, pp. 9, 16.

26 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 14, 80, 87.

27 Department of Agriculture and Water Resources, *Submission 9*, p. 4.

28 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, pp. 4, 34.

29 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–18*, p. 34; Department of Agriculture and Water Resources, *Submission 9*, p. 4.

## Views regarding the impact of the APVMA funding model

### *Evidence regarding APVMA's independence*

3.29 The Committee received considerable evidence that supported the view that the authority is independent. Many witnesses acknowledged that whilst the APVMA was largely funded through fees and levies, this type of system reflected global best practice, was not an unusual arrangement, and did not allow for undue influence in practice.

3.30 Further, evidence suggested the alternative to cost recovery—full public funding—could make the authority subject to the general budgetary decisions of the government of the day and could result in insufficient funding for its regulatory functions.<sup>30</sup> It was also suggested that if there was no financial risk to registrants, 'there is a high probability of poorly conceived registration proposals being submitted. The large number of registrants of generic products in Australia make this a particular concern'.<sup>31</sup>

3.31 The National Farmers' Federation suggested it was a misunderstanding of cost recovery principles to suggest the APVMA could be unduly influenced.<sup>32</sup> Rather, as suggested by a number of submitters, decisions by the APVMA were made within a robust regulatory and science-based framework governed by legislated processes and procedures.<sup>33</sup>

3.32 The Australian Academy of Science explained that the regulator's activities were 'based on formal legislated requirements that provide for decisions informed by expert scientific review. The legislation and supporting administrative arrangements ensure that decisions are based on the best available information'.<sup>34</sup> Further, the Academy:

...considers the APVMA's analyses to be generally open and transparent, well informed and appropriate. Its regulatory decisions with respect to

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30 Associate Professor Christopher Preston, *Submission 19*, p. [2]. There was some support from industry groups for public funding. See, for example: CropLife Australia, *Submission 10*, p. 1; Pastoralists & Graziers Association of Western Australia, *Submission 22*, pp. 4–5.

31 Associate Professor Christopher Preston, *Submission 19*, p. 2. See also: Chemistry Australia, *Submission 17*, p. 3.

32 National Farmers' Federation, *Submission 27*, p. [1].

33 Cotton Australia, *Submission 6*, p. [2]; NSW Farmers' Association, *Submission 8*, p. 10; CropLife Australia, *Submission 10*, p. 5; Grain Producers Australia, *Submission 11*, p. 5; AUSVEG, *Submission 12*, pp. [1–2]; Pastoralists & Graziers Association of Western Australia, *Submission 22*, pp. 3–4; GrainGrowers, *Submission 23*, pp. [1, 5]; National Farmers' Federation, *Submission 27*, p. [1]; Agribusiness Australia, *Submission 30*, p. 8; AgForce Queensland Farmers Limited, *Submission 34*, p. [3]; Primary Industries and Regions SA, *Submission 72*, p. 3; Mr Justin Crosby, Industry and Government Relations, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 30.

34 Australian Academy of Science, *Submission 107*, p. [1].

agricultural chemicals are published on its website and are subject to public scrutiny. Such scrutiny is important for public trust in the agency.<sup>35</sup>

3.33 Similar sentiments with regard to the independence of the regulator's processes were expressed by Bayer Crop Science:

I understand that people feel that, because we are funding the organisation, there might be some conflict there. I don't believe that to be the case whatsoever. There's a very straightforward process by which we deal with our applications and the APVMA deals with our applications.<sup>36</sup>

3.34 Animal Medicines Australia's evidence reflected general industry agreement as to the strength and quality of the authority's work, stating:

We have no concern with the independence of the APVMA. We have concerns with respect to their efficiency and predictability from time to time, but the regulator on the whole is very scientifically based and makes rigorous decisions which are respected around the world.<sup>37</sup>

3.35 Support for the APVMA's science was also expressed by AgForce Queensland who told the Committee:

We believe they are very good with their science. They have very rigorous methods. It is all above board...It is an independent regulator. Like a lot of services offered by regulators, by government, they've got to look at cost recovery.<sup>38</sup>

3.36 The NSW Farmers' Association also voiced its support for the cost recovery model and argued that it ensured an appropriate distribution of the financial burden. It offered the following observations:

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...

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

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35 Australian Academy of Science, *Submission 107*, p. [1].

36 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 3.

37 Mr Ben Stapley, Executive Director, Animal Medicines Australia, *Committee Hansard*, 7 December 2018, p. 39.

38 Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland, *Committee Hansard*, 7 December 2018, p. 57.

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company represents a private good, and this cost should not be fully passed on to government.<sup>39</sup>

3.37 Chemistry Australia acknowledged that whilst suggestions of undue influence were sometimes made, it was of the view:

There isn't corporate influence over the regulatory system...the facts are that we have full confidence that it's independent. Just because our members pay and participate in the scheme doesn't mean every regulatory decision that's made is one that's made in their favour... They're [regulatory scientists at the APVMA] professionals. They have training and education, and they have roles and responsibilities which are legal ones.<sup>40</sup>

3.38 GrainGrowers pointed to the international reputation of the APVMA as evidence of its independence and scientific authority, and indicated:

The strength of the regulatory and compliance measures imposed by the APVMA are recognised internationally through the memorandum of understanding held with New Zealand, and the mutual recognition agreement for good manufacturing practice with nations such as Europe, the US and Canada. Furthermore, the practice of international collaboration to assess specific applications, and use of international assessments reports in work-sharing arrangements, supports independent national risk assessment.<sup>41</sup>

3.39 Submitters identified a number of decisions taken by the regulator—including suspensions of product registrations or changes to label use—which were strongly opposed by some parts of the industry. These included the recent review of 2,4-D label instructions; the 2011 suspension of insecticide products containing dimethoate and the issue of new label instructions that no longer allowed its use on specified food crops; the 2014 cancellation or variation to all registered uses of products containing fenthion, on the grounds the chemical posed unacceptable risks to human and environmental health; and regulatory measures in 2000 including label amendments with updated directions for use, first-aid and safety directions, and environmental warning statements for products containing chlorpyrifos.<sup>42</sup>

3.40 With regard to these decisions, CropLife Australia stated:

While in some cases these decisions may have significant negative consequences for CropLife members or grower industries and attract considerable political and community opposition and media attention, the

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39 NSW Farmers' Association, *Submission 8*, pp. 6, 9.

40 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 49.

41 GrainGrowers, *Submission 23*, p. [3].

42 CropLife Australia, *Submission 10*, pp. 11–12; Grain Producers Australia, *Submission 11*, pp. 2, 5; Pastoralists & Graziers Association of Western Australia, *Submission 22*, p. 2; GrainGrowers, *Submission 23*, p. [3].

APVMA consistently acts in the best interest of the Australian public by committing to science and evidence-based regulatory decisions.<sup>43</sup>

3.41 The Pastoralists & Graziers Association of Western Australia summarised its members' perspectives with regard to the regulator's decisions, arguing:

Despite the not unexpected disagreements between industry and regulator over costs, timeliness, efficiency and access to agricultural chemicals, there is industry support of both the APVMA's independence and its primary role as a regulator.<sup>44</sup>

3.42 There was also support for the impartiality of the funding model, which the Western Australian Farmers Federation argued did not create any incentive to favour the registration of certain chemicals.<sup>45</sup> The NSW Farmers' Association agreed, stating:

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.<sup>46</sup>

3.43 Evidence provided by industry groups suggested there was little opposition from them to the fees and levies charged by the APVMA. Subject to some reservations about the impact of cost recovery on investment in innovation and minor use chemicals (discussed below), there was in fact general support for cost recovery from these industry stakeholders.

3.44 However, some stakeholders stressed the importance of industry being able to engage with the regulator and for timely service in response.<sup>47</sup> The Veterinary Manufacturers and Distributors Association stated:

We accept that, as with other government regulatory entities, the APVMA is virtually a fully cost recovered agency and, while we would be happy to not pay for it, the reality is that we do as required by the legislation. We do, however, wish that the APVMA's performance was more predictable and timely, and to that end we also engage with the regulator to help streamline procedures while accepting the robust assessment and review processes that protect not only the animal population of Australia but also the integrity of our industry...

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43 CropLife Australia, *Submission 10*, p. 1.

44 Pastoralists & Graziers Association of Western Australia, *Submission 22*, p. 6.

45 Western Australian Farmers Federation, *Submission 15*, p. 3.

46 NSW Farmers' Association, *Submission 8*, p. 9.

47 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Australia, *Committee Hansard*, 7 December 2018, p. 33; Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 48; NSW Farmers' Association, *Submission 8*, p. 10; CropLife Australia, *Submission 10*, p. 1; National Farmers' Federation, *Submission 27*, p. [2]; Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 3.

While we'd like to be able to say that we control the regulator, the daily battles of our members with the APVMA in respect of registration applications indicates otherwise. This is genuinely a case of he who pays the piper not calling the tune—and sometimes not even getting to hear the music.<sup>48</sup>

### ***Evidence regarding perceptions of undue influence***

3.45 The Committee received some evidence that suggested the APVMA's funding arrangements and relationships with industry compromised the authority's independence. However, these submitters were not able to provide clear evidence of instances that showed undue influence or bias, or regulatory capture.<sup>49</sup>

3.46 Gene Ethics held the view that:

All regulators have conflicts of interest when they depend on cost recovery from corporate customers to cover their operating costs...Of the APVMA's \$35 million annual budget glyphosate-based herbicides (GBH) contribute about \$1.5 million p.a. This may convey to the public the vivid impression that our regulator has an interest in keeping glyphosate on sale.<sup>50</sup>

3.47 Gene Ethics went on to argue that there was a community expectation that the APVMA be an objective and impartial referee with regard to disputed health, safety and environmental issues. It made the point that the regulatory activities of the APVMA should be conducted at arm's length from industry. It continued:

But the main chemical industry lobby group, CropLife Australia, views the APVMA as a reliable service provider and, in our opinion, directly and indirectly exercises undue influence over both agvet chemical regulatory policy and APVMA practice...It [CropLife Australia] notes that 85 per cent of the chemicals that Australian farmers use are controlled by 16 of CropLife's corporate members, and seven member companies own 100 per cent of crop biotechnology products—that is GM cotton and canola.<sup>51</sup>

3.48 Friends of the Earth Australia similarly identified the funding arrangement as a problem that had 'effectively created a client relationship between the APVMA and industry, and that really needs to be decoupled'.<sup>52</sup>

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48 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Australia, *Committee Hansard*, 7 December 2018, p. 32.

49 For a selection of submitters who expressed concern, see the following: Friends of the Earth Australia, *Submission 35*, p. [4]; Mr Bob Gray, *Submission 47*; Ms Melissa Anderson, *Submission 56*; Mr John Harvey, *Submission 58*; Mr Richard Nankin, *Submission 77*, pp. 3–4; Mr Dean Mensinga, *Submission 79*; Ms Helena Martin, *Submission 86*; Mr John Beale, *Submission 88*; Australian Food Sovereignty Alliance, *Submission 90*, p. 20; Mr Peter Raftos, *Submission 96*.

50 Gene Ethics, *Submission 40*, pp. 2, 8.

51 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, pp. 19, 22.

52 Ms Louise Sales, Emerging Tech Project Coordinator, Friends of the Earth, *Committee Hansard*, 7 December 2018, p. 52.

3.49 The Australian Food Sovereignty Alliance suggested the cost recovery model provided an incentive for the APVMA to encourage industry to create more chemicals and had resulted in regulatory capture where the interests of industry were put above those of the community:

The APVMA's 2012 Cost Recovery Impact Statement (CRIS) shows APVMA are concerned with losing capital and, as a result of product evaluations falling below their 40% target through application fees, increased fees for industry. The logical operation of the APVMA in the current regulatory environment would be to encourage companies to create products for their registration in order to meet targets and increase capital...

A known outcome of regulatory capture is that regulation becomes lenient, putting industry interests above the interests of those the regulator should serve and protect, namely farmers, farmworkers, landscapers, gardeners, everyday consumers and any ordinary citizen who comes into contact with hazardous chemicals.<sup>53</sup>

3.50 The National Toxics Network suggested the APVMA did not act on existing evidence, thus putting the community at risk. It argued that the agvet chemical lobby were 'extremely powerful' and that they were getting what they want while the 'community and the environment pay the price of continued registration and use of dangerous pesticides'.<sup>54</sup>

3.51 Associate Professor Susan Wilson, amongst others, confirmed there was a perception in the wider community that because of the cost recovery strategy, and the actual need for industry to work closely with the APVMA, there was potential for industry to exert undue influence on the application process. Associate Professor Wilson contended that as the APVMA does not undertake any chemical research—the majority of data used for assessments is generated by the applicant or industry—this could also lead to a perception of bias.<sup>55</sup>

3.52 However, Associate Professor Wilson also stated there had definitely been no loss of confidence in the independence of the APVMA and its ability to undertake its regulatory functions 'from the more-informed and academic part of the community'.<sup>56</sup>

3.53 Some submitters called for either an arm's length separation between the regulator and industry or for public funding of the APVMA. Gene Ethics, for example, stated:

We would like the funding of the APVMA by the industry—and it is overwhelmingly funded by the industry—to be much more at arm's length

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53 Australian Food Sovereignty Alliance, *Submission 90*, pp. 20–21.

54 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, p. 25.

55 Associate Professor Susan Wilson and Professor Brian Sindel, *Submission 42*, p. [1]; Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 16.

56 Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 16; CropLife Australia, *Submission 10*, p. 1.

than it is at the moment. Even though the money goes to Treasury, it comes back to the APVMA. We think that the APVMA and other regulators like the OGTR, for instance, should be funded from the public purse and that any revenues should be delinked from the regulator that 'benefits' from the industry's input.<sup>57</sup>

3.54 This was a suggestion also raised by Associate Professor Wilson. While she did not believe that there was undue influence, she recognised the importance of creating trust within the community, stating:

It's a difficult problem to answer. Possibly by having some component that's publicly funded or having an arm's length entity to manage the fee payment rather than all of that being handled within that one grouping. There is a loss of trust, especially with everything that's in the media at the moment. Building community trust and building community understanding would help significantly.<sup>58</sup>

### **Access to chemicals and veterinary medicines in Australia**

3.55 The Committee was told that several factors discouraged some companies from applying to either register their products in Australia, or reduce the uses for which they applied. These factors included the small size of the Australian market (approximately 1.5 per cent of the global market), the fact Australia is no longer on the global priority list for pesticide and veterinary medicine investment in commercialisation, and the cost of registration.<sup>59</sup>

3.56 Grain Producers Australia provided research comparing the first registered labels between Australia and the United States for several compounds. Although a direct comparison was not possible as the particular local conditions and regulations that led to the approvals was not clear, the results are summarised in Table 3.2.

3.57 Table 3.2 shows that in the larger market of the United States, in some cases applicants register a significantly larger number of uses.

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57 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 22.

58 Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 16.

59 Grain Producers Australia, *Submission 11*, p. 10; Associate Professor Christopher Preston, *Submission 19*, pp. 2–3; National Farmers' Federation, *Submission 27*, p. 3; Victorian Farmers Federation, *Submission 33*, pp. [4–5]; AgForce Queensland Farmers Limited, *Submission 34*, pp. [4–5]; Mr David Mailler, Chair, Agricultural Science Committee, NSW Farmers' Association, *Committee Hansard*, 20 November, p. 16; Mr Chris Groves, Chair, Farming Systems Committee, National Farmers' Federation, Vice President, NSW Farmers' Association, *Committee Hansard*, 20 November 2018, p. 17; Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 30.

**Table 3.2—Comparison of first registered labels between Australia and the United States**

Compound	Number of initial registered uses	
	Australia	United States
Penflufen	2	10
Sedaxane	4*	4*
Penthiopyrad	10	22
Fluxapyroxad	1	21
Prosulfuron	1	3
Saflufenacil	1	13
Pyroxasulfone	2*	2*
Foramsulfuron	1	2

\* registered uses differed; *Grain Producers Australia*.<sup>60</sup>

3.58 GrainGrowers explained the problems caused by various factors in the Australian marketplace:

Given the small size of the Australia market, and the extent of global chemical development and manufacturing, Australian farmers are inherently disadvantaged in the range of chemicals they can access compared to growers in other countries. Put simply, the lower commercial return available in Australia compared to larger markets results in products never being submitted for registration or a delay in submitting for registration in Australia.<sup>61</sup>

3.59 Grain Producers Australia added its concerns over the negative impact of the small market in Australia, arguing:

Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China...

Growers are impacted by the 'double whammy' of lack of new, more advanced pesticide options delivering productivity outcomes, plus accelerated selection pressure for pesticide resistance due to a narrow pool of products.<sup>62</sup>

60 Grain Producers Australia, *Submission 11*, p. 10.

61 GrainGrowers, *Submission 23*, p. 6.

62 Grain Producers Australia, *Submission 11*, pp. 10–11.

3.60 From the perspective of chemical companies and in response to suggestions about raising the costs of registration in Australia, CropLife Australia suggested to the Committee:

...the Australian market is one-tenth the size of the US market, but the regulatory system costs the same, dollar for dollar. So we immediately have a serious hurdle in terms of ensuring that Australian farmers have access to products in the same timely manner as around the world. A new chemical product, from beginning to end, now costs more than US\$256 million and 11 years in R&D to bring to market, and a third of those costs are now directly related to regulatory systems. So the reason that we are cautious on adding any new costs to the regulatory system is that it has genuine, real consequences to farmers' access to innovation in the first place and what they pay. It's not this view that it would just be the chemical companies that pay for it. It builds into the whole of the costs that end up on farm for production.<sup>63</sup>

3.61 The APVMA has recognised that registration and assessment costs can outweigh the benefits of commercialising new products for certain low-volume use chemicals, or in emergency situations. The minor use permit system allows chemicals that are not registered to be permitted for 'minor uses'. This permits the use of agvet chemicals without the full cost of registration.<sup>64</sup>

3.62 The use of this system was explained by AgForce Queensland:

The APVMA has regulatory provisions for off-label use of agvet chemicals through emergency and minor use permits. This regulatory pathway must be retained to enable rapid response to new biosecurity pest, weed or disease incursion. For example, agvet chemical companies are reluctant to invest in changing product labels for emerging weeds that must be rapidly controlled. Often there is very little return on investment for agvet chemical companies to add certain weed species to labels for rangeland weeds in non-crop areas and certain application methods for roadsides, waterways. The APVMA minor use permit system can accommodate these niche situations.<sup>65</sup>

3.63 Some submitters argued that both the fees and data requirements for minor use permits remain too onerous and undermined the intent of the program to protect consumers and prevent industry loss.<sup>66</sup> Associate Professor Christopher Preston also advised that the intent of the program was not always realised:

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63 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, p. 59.

64 Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 306.

65 AgForce Queensland Farmers Limited, *Submission 34*, pp. [4–5].

66 Western Australian Farmers Federation, *Submission 15*, p. 3; Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland Farmers Limited, *Committee Hansard*, 7 December 2018, p. 60. See similar comments for off-label permits: South Australian Department of Primary Industries & Regions, *Submission 72*, p. 3.

Australia has a permit system that is regularly used to allow additional products to be used by growers of minor crops; however, that system has the intention that the permit uses will be moved onto labels. In practice this too often does not happen due to a lack of willingness by registrants to invest in minor crop use.<sup>67</sup>

3.64 With regard to the costs of minor use permits, CropLife Australia stated:

In the case of minor and specialty crops, this cost of developing the necessary supporting data to meet due diligence and regulatory requirements far exceeds any potential return on investment. Similarly, the financial burden on grower groups to generate the necessary data to support an application for a minor use permit is often prohibitive. As a result, Australian producers of specialty food and minor crops are faced with numerous challenges in managing plant pests, weeds and diseases.<sup>68</sup>

3.65 This view was supported by Cotton Australia, which argued the process to apply for permits was not efficient and had the potential to endanger safety through off-label use:

Cotton Australia applies for a number of permits on behalf of its growers to cover specialty use situations that are not covered by established approved chemical use patterns. The lengthy time frames (often over 12 months) for having these minor use permits approved, or amended, is prohibitive to productivity. This is especially the case when emergency permits for new pest outbreaks are required. The prohibitive cost and time frames results in producers having to use products 'off-label'. The use of products in an unregulated, off-label situation creates potential risks with product safety, efficacy and resistance management for the whole Australian community.<sup>69</sup>

3.66 Submitters suggested a number of ways to deal with the issue of high costs. For example, Grain Producers Australia stated:

...the application fee should be set at a level that balances the ability for the APVMA to recover a portion of the cost of assessment upfront while not acting as a significant disincentive for users to seek a minor use permit for off-label use of an agvet chemical.<sup>70</sup>

3.67 GrainGrowers argued that Australia's chemical assessment and registration processes should be made as efficient and rigorous as possible to allow farmers to access new chemistry in a timely manner to maintain competitive advantage. GrainGrowers further observed:

The APVMA does not rely on international registration of products to a sufficient extent, thus duplicating the assessment of the same product's

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67 Associate Professor Christopher Preston, *Submission 19*, pp. 2–3.

68 CropLife Australia, *Submission 10*, p. 15. See also: Cotton Australia, *Submission 6*, p. 2; Agribusiness Australia, *Submission 30*, p. 7.

69 Cotton Australia, *Submission 6*, p. 2.

70 Grain Producers Australia, *Submission 11*, p. 7.

registration in Australia despite it being registered in many other countries.<sup>71</sup>

3.68 The Western Australian Farmers Federation encouraged the APVMA to refine the application process for minor use permits through the adoption of a digital application process and a more pragmatic approach to the detailed evidence required for the application.<sup>72</sup>

3.69 Agribusiness Australia highlighted an existing DAWR program that assisted with the costs of registrations for minor uses: the Improved Access to Agvet Chemicals Initiative. Agribusiness Australia stated the program helped alleviate regulation-generated market failure. It was noted this type of market failure often resulted from the high costs associated with registering products for minor uses that could not be offset by volume of sales.<sup>73</sup>

3.70 The Improved Access to Agricultural and Veterinary Chemicals Initiative, which was established in 2014 (with \$8 million in funding to the end of the 2017–18 financial year), had several purposes, including:

- establishing an agvet collaborative forum to allow stakeholders to share access needs with each other and chemical companies;
- creating an official Australian crop grouping list and associated APVMA guidelines;
- migrating some APVMA permits to product labels; and
- developing an assistance grants program to help fund the generation of sufficient data to support applications to the APVMA.<sup>74</sup>

3.71 Some submitters presented an alternative to promoting the increased availability of chemicals, arguing for the adoption of alternative and smaller farming practices over seeking new chemical solutions.<sup>75</sup> The Australian Food Sovereignty Alliance, for example, argued:

Despite the glaring need for a transition to ecological agriculture, agvet chemical use is increasing. Governments and regulators continue to

71 GrainGrowers, *Submission 23*, p. [6]. See also: Victorian Farmers Federation, *Submission 30*, p. [5].

72 Western Australian Farmers Federation, *Submission 15*, p. 3.

73 Agribusiness Australia, *Submission 30*, p. 7.

74 Department of Agriculture and Water Resources, *Improved Access to Agricultural and Veterinary Chemicals – \$8 million initiative*, <http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/improved-access-agvet-chemicals#about-the-new-funding> (accessed 10 January 2019); Australian Pesticides and Veterinary Medicines Authority, *The Crop Groupings Project*, <https://apvma.gov.au/node/18851> (accessed 10 January 2019).

75 See, for example: Local Environment Action Forum, *Submission 14*, p. 5; Mr Duncan Mills, *Submission 20*, p. 2; Ms Jessica Harrison, *Submission 37: Attachment*, p. [1]; Gene Ethics, *Submission 40*, p. 16; Pesticide Action Group WA, *Submission 104*, p. 21; M and P Wilson, *Submission 108*, p. [3].

facilitate pesticide industry claims to dictate the future of our food system. The number of small farms in Australia is decreasing, with only 10% of farms producing over half of our agricultural output, and more large farms consolidating to respond to pressures on the agribusiness industry.<sup>76</sup>

3.72 The Australian Food Sovereignty Alliance also called for government support for the development of:

...businesses that create, sell and use sustainable alternatives to agvet chemicals, including agroecology and regenerative agriculture, organic alternatives to weed, insect and other pest management, and traditional agricultural pesticides, herbicides, fungicides and potentially veterinary solutions.<sup>77</sup>

### **Greater efficiency through the use of international data**

3.73 A number of submitters argued that more efficient and faster processing of applications would occur if the APVMA made greater use of international data and assessments within a risk-based assessment framework.<sup>78</sup>

3.74 However, in calling for greater acceptance of international data, submitters were not of the view that Australia should automatically recognise or abide by the decisions of regulators from other jurisdictions.<sup>79</sup>

3.75 The NSW Farmers' Association emphasised the need for an Australian regulator to consider the unique circumstances of Australian agriculture and the applicability of particular chemicals or veterinary medicines to the Australian environment. The association stated there had to be:

...an appropriate balance between referencing the approval process that has been relied upon internationally and the science that has been used to underpin some of those things, but then to make sure that that doesn't mean that when, for example, a European regulator coughs, Australia necessarily catches a cold when it comes to the application of that chemistry in this market.<sup>80</sup>

3.76 It was suggested by the NSW Farmers' Association that the automatic acceptance of decisions made in other jurisdictions could lead to less stable decision

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76 Australian Food Sovereignty Alliance, *Submission 90*, p. 6.

77 Australian Food Sovereignty Alliance, *Submission 90*, p. 28.

78 Grain Producers Australia, *Submission 11*, pp. 12–14; Western Australian Farmers Federation, *Submission 15*, p. 2; GrainGrowers, *Submission 23*, pp. 3, 6; Australian Dairy Industry Council and Dairy Australia, *Submission 25*, p. 2.

79 See, for example: Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, pp. 60–61.

80 Mr Robert Hardie, Policy Director, Environment, Cropping and Horticulture, NSW Farmers' Association, *Committee Hansard*, 20 November 2018, p. 18.

making and increase the risk of the politicisation of the approval of chemicals for use by the farm sector.<sup>81</sup>

3.77 The trade implications of using international data were identified by the National Farmers' Federation, which stated:

The APVMA also does a trade assessment, a market assessment, when it assesses chemicals, and that's important to note, because, I think you would acknowledge, other regulators don't necessarily service the same markets that Australia does. There are certainly members within our remit that would like to see that trade assessment remain, even with the acknowledgement of international processes. And that's pretty important. You can imagine a scenario where a product is approved in one country but they may not export to the same markets we do, so that's important to be taken into account in that process.<sup>82</sup>

3.78 The APVMA previously agreed it was necessary to consider Australian situations and circumstances, providing the example that conditions placed on herbicides used in the EU would probably not be automatically transposed to herbicide use in tropical Queensland, due to requirements of state legislation to protect the Great Barrier Reef.<sup>83</sup>

3.79 The Committee was informed the APVMA already participated in a global joint registration program, which aimed to improve the efficiency and effectiveness of the registration process by sharing data amongst participants. It also had a mutual recognition agreement with some regulators from Europe, Canada, New Zealand and the United States with regard to manufacturing standards.<sup>84</sup>

3.80 Over recent years, the APVMA has been moving towards making greater use of international data and assessments and has made provisions for international work sharing. The regulator is participating in an Organisation for Economic Cooperation and Development process to establish a framework for global joint reviews; and has undertaken collaborative regulatory assessments of veterinary medicines with Canadian and New Zealand authorities.<sup>85</sup>

3.81 Further, APVMA CEO, Dr Parker, recently issued a direction that detailed the expectations of the APVMA in relation to the use of international data, standards and

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81 NSW Farmers' Association, *Submission 8*, pp. 7–8.

82 Mr Mark Harvey-Sutton, General Manager Rural Affairs, National Farmers' Federation, *Committee Hansard*, 20 November 2018, p. 18.

83 Australian Pesticides and Veterinary Medicines Authority quoted in, Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p. 302.

84 Western Australia Department of Primary Industries and Regional Development, *Submission 16*, p. 2; AgForce Queensland Farmers Limited, *Submission 34*, p. [3]; Australian Pesticides and Veterinary Medicines Authority, *Recognition of Overseas GMP Authorities*, <https://apvma.gov.au/node/141> (accessed 4 January 2019).

85 Australian Pesticides and Veterinary Medicines Authority, *Collaborative and International Assessments Including Work-Sharing*, <https://apvma.gov.au/node/1053> (accessed 10 January 2019).

assessments.<sup>86</sup> This legal direction requires APVMA staff to maximise the use of international assessments supplied with an application in order to improve the efficiency and timeliness of the APVMA's assessments.<sup>87</sup>

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86 Australian Pesticides and Veterinary Medicines Authority, *CEO Expectations on Use of International Data, Standards and Assessments*, 20 June 2018, [https://apvma.gov.au/sites/default/files/publication/26886-26886-revised\\_ceo\\_expectations\\_for\\_use\\_of\\_international\\_data\\_standards\\_assessment\\_ceo\\_approved\\_final\\_1.pdf](https://apvma.gov.au/sites/default/files/publication/26886-26886-revised_ceo_expectations_for_use_of_international_data_standards_assessment_ceo_approved_final_1.pdf) (accessed 4 January 2019).

87 Australian Government, *Productivity Commission Inquiry into the Regulation of Australian Agriculture: Australian Government Response*, January 2019, p. 11.