Department of Agriculture

First Principles Review of Cost Recovery at the Australian Pesticides & Veterinary Medicines Authority

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Contents

1. Executive Summary

1.1. Current Cost Recovery Framework

The Australian Pesticides and Veterinary Medicines Authority (the APVMA) is the independent Australian government statutory authority responsible for the assessment, registration and monitoring of agricultural and veterinary chemicals (agvet chemicals) and for their regulation up to and including the point of retail sale.

The APVMA is currently funded largely on a cost recovered basis from registrants of agvet chemicals. These cost recovery arrangements were established through a policy under which the APVMA collects, for most applications, an upfront application fee comprising 40 per cent of the cost of processing the application. The APVMA recovers the remainder of these costs through a levy based on product sales with specific levy rates applicable to three tiers of annual product sales revenue. The levy is also used as a balancing factor in order to enable the APVMA to cover costs where the fee for an activity is insufficient, or where it is otherwise inefficient or inequitable to recover by a direct fee. This cost recovery arrangement was established to foster innovation and not disadvantage smaller companies with high upfront fees[1]. Additionally the APVMA charges an annual fee of $430 for each registered product in order for the product to remain on the register for the upcoming year.

1.2. Purpose of the First Principles Review

The APVMA's current cost recovery framework was established in 1996 and has not been comprehensively reviewed since that time. There have been continuing representations from industry that the current cost recovery arrangements do not support the agvet chemicals industry.

Protiviti was engaged by the Department of Agriculture to conduct a first-principles review of cost recovery at the APVMA (the Review). The objective of the Review was to conduct an independent assessment of the APVMA's cost recovery arrangements and recommend an appropriate cost recovery framework. The Review was to examine options to strengthen the financial sustainability, transparency and accountability of the APVMA's cost recovery arrangements.

In evaluating an appropriate cost recovery framework, the Review considered several critical matters, including consistency with the Australian Government Cost Recovery Guidelines 2005 (the Cost Recovery Guidelines) and the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) objectives[2].

1.3. Recommended Cost Recovery Framework

The Review recommends a fundamental shift in the cost recovery framework of the APVMA to reduce its reliance on cross-subsidisation (through the levy based on product sales). We recommend the following general elements as the foundation for the framework:

- Upfront fees for activities where the direct costs can be reasonably attributed to a specific user of the service, such as the costs of assessing applications for product registration. To reduce the impact of the upfront fees on applicants, for fees above a threshold limit, applicants should have the option to either pay the full fee up front or pay by instalments with a fee adjustment to reflect the cost of administering the instalment payment arrangement.
- Some exceptions have been made where partial or full subsidisation of fees is necessary to prevent perverse outcomes. Specifically, the framework subsidises the application fee and any pre-application advice sought for minor and emergency use permits in order to support the intent of these programs, with applicants contributing only a portion of the cost of assessment for minor use permits. The remainder of these costs are recovered from industry by way of a tiered annual flat levy on each registered product, as discussed below.

[1] The APVMA – Cost Recovery Discussion Paper (December 2011)
[2] The NRS was established to ensure agvet chemicals are effective, labelled and packaged correctly, safe to humans and non-target species and do not pose a risk to the environment

- An annual levy for each activity where it is not practical to attribute individual costs, such as compliance monitoring, investigation, enforcement and other general activities. These levies should be tiered based on the value of agvet chemical product sales during the preceding year to recognise the need to assist the continued supply of products, particularly those with low levels of sales.
- Introduction of government funding for the APVMA's activities in informing policy in accordance with the principle of the Cost Recovery Guidelines that costs not directly related to the provision of products or services should not be recovered.
- Maintenance of the APVMA's financial reserve to support financial viability in managing short term fluctuations in the level of activity.
- Regular monitoring and adjustment of fees and charges in line with changes in expenditure rather than automatic indexation.

The following table outlines the cost recovery framework recommended by the Review.

Activity	Recommended Model
Registration and Approvals	
Product and Active-Constituent Registrations and Approvals	
Applications for product registration, approval of active constituents and major variations, minor changes requested by applicants	An upfront application fee is charged based on the average cost of assessing an application of that type or module.
Minor changes required by the APVMA	An upfront application fee is charged based on the average cost of assessing an application for minor changes.
Permits	
Permits for possession and export and extensions of export permits	An upfront application fee is changed based on the average cost of assessing an application for a permit for possession and export. For permit extensions, an upfront application fee is changed based on the average cost of assessing an application for a permit extension.
Minor use permits and extensions of minor use permits	An upfront application fee is charged as a small contribution to the cost of assessing a minor use permit or a permit extension, with most of the costs being recovered through a specific identifiable tiered annual flat levy that is charged on all registered products.
Emergency use permits and extensions of emergency use permits	A specific tiered annual flat levy is charged on all registered products to recover the costs of assessing emergency use permits and permit extensions.
Research permits and extensions of research permits	An upfront application fee is charged based on the average cost of assessing an application of that type or module. For permit extensions, an upfront application fee is charged based on the average cost of issuing an extension of the permit for each applicable module.
Miscellaneous permits and extensions of miscellaneous permits	An upfront application fee is charged based on the average cost of assessing an application of that type or module. For permit extensions, an upfront application fee is charged based on the average cost of issuing an extension of the permit for each applicable module.

Activity	Recommended Model
Application Advice	
Pre-application advice	An upfront standard fee is charged for each request for advice based on the average cost of administratively processing the request and issuing an estimate of the likely fee in providing the requested advice. An hourly rate is charged for conducting research, obtaining further information from the requestor and the provision of advice. The applicant would also be charged the hourly rate for any additional advice sought beyond the initial request. Where pre-application advice is sought in relation to an application that has a subsidised fee (being for a minor or emergency use permit), the upfront fee and hourly rate should be subsidised in a consistent manner. The fee charged is not rebated on submission of an application.
Other Market Activities	
Certificates of Export	An upfront application fee is charged based on the average cost of assessing an application for Certificates of Export.
Consents to Import	An upfront application fee is charged based on the average cost of assessing an application for Consents to Import.
Monitoring Ongoing Compliance with Regulations and Investigation and Enforcement	
Manufacturing Standards of Agvet Chemicals	
Compliance with standards for the manufacture of veterinary chemicals (such as the current Manufacturing Licence Scheme (MLS) and the Overseas Good Manufacturing Practice (GMP) Scheme)	For Australian manufacturers of veterinary medicines, an upfront application fee is charged for a licence to manufacture based on the average cost of assessing an application. An additional specific categorised annual levy is charged based on average cost to confirm compliance for manufacturing processes differing in complexity. For any variations to licences, an additional fee is charged if the APVMA determines that an audit is required. This additional fee is based on the average cost of reviewing the audit. For veterinary medicines manufactured overseas, the local registrant of the product is required to pay a tiered annual flat levy based on the average cost to confirm compliance for manufacturing sites outside Australia.
Compliance with standards for the manufacture of agricultural chemicals (such as the current agricultural chemical products Quality Assurance (AgQA) Scheme)	A specific annual flat levy is charged on each registered agricultural chemical product.
Other Compliance Monitoring, Investigation and Enforcement Activities	
Regulation of the supply of particular products (such as the current Hormonal Growth Promotant Scheme (HGP))	An upfront application fee is charged based on the average cost of assessing an application for a licence to supply a particular product. A flat tiered annual licence renewal levy charged to licence holders to recover the full cost of maintaining the scheme.
System for the public to provide feedback on agvet chemicals (such as the current Adverse Experience Reporting Program (AERP)) and programs for the APVMA to conduct reviews of registered chemicals (such as the current Chemical Review Program) and undertake compliance and enforcement action	A specific tiered annual flat levy is charged on all registered products.

Activity	Recommended Model
General Activities	
Website, annual report and corporate publications, consultative committees, presentations and seminars and the information publishing scheme	A specific tiered annual flat levy is charged on all registered products.
Informing policy (including Senate estimate hearings, Questions on Notice, Ministerial briefings)	Government appropriation
Research (i.e. Principal Scientists)	A specific tiered annual flat levy is charged on all registered products. The levy charged is offset by any government appropriation provided to the APVMA for specific research activities.

Other Recommendations

Recommendation 1

We recommend that applicants are offered a discount for upfront payment of a fee where they are eligible for payment in instalments but elect to pay upfront. This discount should reflect the cost of administering a more complex instalment payment scheme.

Recommendation 2

We recommend that the annual levy charged be comprised of separate identifiable fees for each type of activity in order to allow registrants to appreciate the proportion of costs recovered for each activity conducted by the APVMA.

Recommendation 3

As the recommended framework can result in a significant increase in the annual flat levies charged for a range of activities, we recommend that the levies be tiered based on the value of agvet chemical product sales during the preceding year.

For the current MLS, we recommend that the categorised annual fee be tiered based on the total notional wholesale value of chemical products manufactured during the preceding year as manufacturers (rather than registrants) are charged the annual levy.

Recommendation 4

We recommend that for any application withdrawal, the applicant is charged a proportion of the application fee based on the costs incurred by the APVMA in assessing the application prior to notification of the withdrawal.

Recommendation 5

The APVMA should monitor the level of non-compliance with requirements relating to consents to import through its compliance and enforcement processes. Should there be a significant increase in the level of non-compliance, the APVMA should conduct a detailed review to identify the root causes relating to the detected instances of non-compliance.

Recommendation 6

We recommend the continuation of the APVMA's reserve mechanism in order for the APVMA to maintain financial viability in managing short term fluctuations of its activity.

Recommendation 7

We recommend that the APVMA's fees are not subject to any automatic indexation.

1.4. Rationale for the Recommended Framework

The framework recommended by the Review balances critical matters in setting an appropriate arrangement for cost recovery at the APVMA, including the following:

- Improving the alignment of APVMA's cost recovery arrangements with the Cost Recovery Guidelines. In particular, the key change of removing the uncapped sales levy addresses many of the cross-subsidisation concerns for recovering the cost of assessing applications and increases the transparency of the cost recovery arrangements.
- Providing mechanisms to allow applicants flexibility in managing application costs by permitting payment of application fees above a threshold in instalments.
- Recognising the potential for perverse outcomes from full cost recovery of application fees for minor use and emergency use permits and provides a way to fund these activities that limits impacts on access to agvet chemicals.
- Supporting the continued supply of registered products, and in particular products with low levels of sales, through tiering the annual flat levy for compliance monitoring, investigation, enforcement and other general activities.
- Supporting the financial sustainability of the APVMA through aligning activities with cost drivers of the APVMA.
- Providing a way for the APVMA to recover the full cost of its activities in a manner that is efficient, transparent and accountable.

2. Background

2.1. Agvet Chemicals Industry

The agvet chemicals industry is a diverse industry comprising importers, manufacturers, packagers, wholesalers and retailers of a variety of products, including veterinary medicines, companion animal products, pesticides and other agricultural products, chemicals for home garden and household use, pool and spa chemicals, timber preservatives and marine anti-fouling paints.

The Australian agvet chemicals industry is dominated by a few major multinational companies. The Australian pesticide manufacturing industry is dominated by the following companies, who collectively make up over 80 per cent of the market[3]:

- Nufarm Limited;
- Syngenta Crop Protection Pty Ltd; and
- Bayer CropScience Pty Ltd.

The Australian veterinary pharmaceuticals manufacturing industry is dominated by the following companies, who collectively make up over 75 per cent of the market[4]:

- Virbac (Australia) Pty Ltd;
- Pfizer Australia Holdings Pty Limited;
- Intervet Schering-Plough Animal Health Pty Ltd; and
- Jurox Pty Ltd.

The wholesale value of veterinary product sales tends to be relatively stable, whereas the wholesale value of agricultural product sales is closely linked to seasonal conditions.

2.2. Role of the APVMA

The APVMA is the independent Australian government statutory authority responsible for the assessment, registration and monitoring of agvet chemicals and for their regulation up to and including the point of retail sale. The regulatory framework for managing agvet chemicals in Australia is collectively referred to as the NRS. The APVMA administers the NRS in partnership with state and territory government agencies and in collaboration with other Commonwealth agencies.

The APVMA operates according to its governing legislation, the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act) and the *Agricultural and Veterinary Chemicals Code 1994* (the Agvet Code). The APVMA is authorised to charge levies for the sale of agvet chemical products under the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*.

2.3. Current Cost Recovery Arrangements

The APVMA is one of a number of Australian Government regulators funded by fees and charges imposed on the industry it regulates. Under the agreement that established the NRS, the Australian Government and all state and territory governments determined that the APVMA should operate on a fully cost recovered basis, which it has done since 1996.

The basis for this cost recovery framework was determined by the Signatories Working Group (SWG) and endorsed by the Primary Industries Standing Committee (PISC) in July 2002. The SWG was comprised of representatives of Commonwealth, State and Territory governments. This established a policy under which the APVMA would collect, for most applications, an upfront application fee comprising 40 per cent of the cost of processing the application. The APVMA would recover the

[3] IBIS World Industry Report - Pesticide Manufacturing in Australia (March 2013)
[4] IBIS World Industry Report – Veterinary Pharmaceutical Manufacturing in Australia (March 2013)

remainder of the costs through a levy based on product sales. The SWG determined that this approach would foster innovation and not disadvantage smaller companies with high upfront fees[5].

The levy is also used as a balancing factor in order to enable the APVMA to cover costs where the fee for an activity is insufficient, or where it is otherwise inefficient or inequitable to recover by a direct fee. Specific levy rates are applicable to three tiers of annual product sales revenue. No levy is collected on annual product sales revenue of up to $5,000[6] and there is no cap on the amount of levy collected for sales that exceed this value. Additionally the APVMA charges an annual fee of $430 for each registered product in order for the product to remain on the register for the upcoming year.

The cost of the activities conducted during the 2011-12 financial year have been used as the basis for analysis in this report as the broad cost levels and proportions of activity have remained unchanged. Additional commentary has been provided where a significant change in the activities has been noted for subsequent years. Appendix 1 of this report provides details of the revenue received and expenditure incurred by the APVMA during the year ended 30 June 2012.

2.4. Principles of Cost Recovery

An equitable cost recovery activity is designed to recover, in full, direct and indirect costs of provision of a government good, service or regulation.

The Cost Recovery Guidelines establish a set of 14 key principles to be adopted in cost recovery arrangements across the Australian government. Details of these principles have been provided in Appendix 2 of this report.

These principles state that agencies should set charges to recover all the costs of products or services where it is efficient to do so. The costs of an activity should be recovered from those who use or create the need for the activity. The charges should be reflective of the costs of providing the service and should generally be imposed on a fee-for-service basis or, where it is more efficient to do so, as a levy. Costs that are not directly related or integral to the provision of products or services should not be recovered. Agencies should not cost recover where it is inconsistent with explicit government policy objectives, government-endorsed community service obligations or where it would unduly stifle competition or industry innovation.

The Cost Recovery Guidelines state that agencies should ensure there is a clear legislative basis for the imposition of fees and charges.

2.5. Background to the First Principles Review

There have been continuing representations from industry that the APVMA's current cost recovery arrangements do not support the agvet chemicals industry. The structural robustness of the cost recovery framework as a whole has not been comprehensively reviewed since it was first initiated. Some aspects of the APMVA's cost recovery arrangements have been periodically examined, mainly as a result of amendments to the agvet chemical legislation and new regulatory activities.

Several issues arise when examining the existing cost recovery arrangements of the APVMA.

- The current splitting of the recovery of application assessment costs between up front application fees (nominally 40 per cent) and an ongoing levy on product sales has not been evaluated since its introduction.
- The current structure of the sales levy results in a large amount of the APVMA's costs incurred in assessing applications being paid by the registrants of a small number of high selling products.
- Costs of some other services, including consents to import, minor use permits and emergency permits, are not fully recovered directly from applicants. Rather, these costs are funded through the sales levy, which may not be the most efficient and transparent method of cost recovery for these services.

[5] The APVMA – Cost Recovery Discussion Paper (December 2011)
[6] It has been considered inefficient to collect a levy for products with annual sales of $5,000 or less

- Stakeholders have indicated concern as to the legitimacy of the public funding of some activities, such as the AERP and compliance. Although it has been considered and rejected in previous cost recovery reviews, this review provided a further opportunity to examine the issue.

In light of these considerations, in 2012 the Department of Agriculture was asked by the Government to undertake the Review of the APVMA's cost recovery framework, in consultation with state and territory governments and other stakeholders.

2.6. Objective and Scope

The objective of the Review was to conduct an independent assessment of the APVMA's cost recovery arrangements and recommend an appropriate cost recovery framework. This included examining options to strengthen the financial sustainability, transparency and accountability of the APVMA's cost recovery arrangements. The Review was not limited by the legislative framework applicable to the current cost recovery arrangements at the APVMA.

The scope of the Review included consideration of a cost recovery approach that covers the cost of all of the APVMA regulatory obligations and services. The Review focused on identifying a structure in which:

- Costs are being recovered while minimising cross-subsidisation;
- Costs are appropriately borne by the users of each service or by those who create the need for the regulatory activity;
- Cost recovery arrangements are consistent with the Cost Recovery Guidelines;
- Cost recovery arrangements operate in a manner which most effectively supports the NRS objectives[7]; and
- The cost recovery arrangements support ongoing financial viability and sound financial governance of the APVMA.

In order to do so, the Review:

- Assessed the manner in which the regulatory activities of the APVMA for agvet chemicals were funded;
- Qualitatively analysed the impacts of proposed alternative cost recovery options on industry; and
- Considered the available APVMA cost recovery and financial information up to the year ended 30 June 2012. Additionally, we considered recent developments in relation to the Better Regulation of Agricultural Chemicals and Veterinary Medicines reforms[8] and the CRIS 2013-2015[9].

Scope Limitations

The Review did not:

- Consider changing the scope and nature of the APVMA's regulatory activities;
- Assess whether the APVMA's regulatory activities are efficient or effective;
- Conduct detailed quantitative economic modelling to assess the impacts of the proposed cost recovery framework; or
- Encompass any potential changes the Finance Minister may make to the Australian government Cost Recovery Framework.

[7] The NRS was established to ensure agvet chemicals are effective, labelled and packaged correctly, safe to humans and non-target species and do not pose a risk to the environment or unduly prejudice trade
[8] Further details of these reforms can be found at http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals.
[9] http://www.apvma.gov.au/about/work/cost_recovery.php

2.7. Approach

This Review included the following activities:

- Preliminary data gathering, including understanding the APVMA's activities and business processes, and identification of key issues[10];
- Defining current cost recovery arrangements through review of existing APVMA documentation such as the CRIS 2013 – 2015 and discussion papers;
- Reviewing industry submissions in relation to the Review and Cost Recovery Discussions papers and consultation with industry representatives (a list of industry bodies contacted during the review is included at Appendix 3);
- Conducting comparative analysis of the APVMA's cost recovery arrangements against other regulatory agencies, both locally and internationally (a list of agencies consulted is outlined at Appendix 2[11]);
- Analysing the APVMA's cost recovery process maps, activity-based costing model and Fees Review model to ensure that the methodology and assumptions were appropriate;
- Identifying and analysing potential cost recovery models for the APVMA through lessons drawn from the benchmarking activity defined above. In conducting this analysis, we considered a range of viable options for funding each type of activity, including variants or combinations of the following core mechanisms:
    - Fee for service based on the direct or average cost of conducting an activity;
    - Flat fee or levy applicable to all or a subset of all registrants or approval holders;
    - Levy reflecting presence in the market (a proxy for which can be sales); and
    - Government funding for conducting an activity.

  The analysis conducted included evaluation of each of these mechanisms against the criteria stated in section 2.6 of this report;
- Developing a consultation paper that detailed our analysis of the potential cost recovery models for comment and public consultation[12]; and
- Considering public submissions on the consultation paper[13].

[10] The Review drew upon the activity-based costing work previously undertaken for the APVMA by PricewaterhouseCoopers (PwC). Our review of the Activity-Based Cost and Fees Review Models indicated that the models were suitable for obtaining an understanding of the APVMA's activities and provided context during the analysis of potential alternative cost recovery models for the purposes of the Review.

[11] The purpose of benchmarking the APVMA's cost recovery arrangements was to inform the Review of alternate ways in which regulatory agencies cost recover. Where relevant for the consideration of a potential cost recovery model for a given activity, the outcomes from our discussions with the regulatory bodies have been drawn on in the Analysis of Potential Models Section below.

[12] The consultation paper is available at http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/first-principles-review-of-the-apvmas-cost-recovery-arrangements.

[13] Submissions received on the consultation paper are available at http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/first-principles-review-of-the-apvmas-cost-recovery-arrangements/submissions-received.

3. Overview of Recommended Framework

A summary of the recommended cost recovery framework has been provided in section 3.1 of this report, with additional information on the framework by activity type detailed in section 4. In general, the Review recommends a fundamental shift in the cost recovery framework of the APVMA to reduce its reliance cross subsidisation (through the levy on product sales). We recommend the following elements as the foundation for the framework:

- Upfront fees for activities where the direct costs can be reasonably attributed to a specific user of the service, such as the costs of assessing applications for product registration. To reduce the impact of the upfront fees on applicants, for fees above a threshold limit, applicants should have the option to either pay the full fee up front or pay by instalments with a fee adjustment to reflect the cost of administering the instalment payment arrangement.
- Some exceptions have been made where partial or full subsidisation of fees is necessary to prevent perverse outcomes. Specifically, subsidisation of the application fee and pre-application advice sought for minor and emergency use permits in order to support the intent of these programs, with applicants contributing only a portion of the cost of assessment for minor use permits. The remainder of these costs are recovered from the industry by way of a tiered annual flat levy on each registered product, as discussed in section 3.2.
- An annual flat levy for each activity where it is not practical to attribute individual costs, such as compliance monitoring, investigation, enforcement and other general activities. These levies are tiered based on the value of agvet chemical product sales during the preceding year to recognise the need to assist the continued supply of products, particularly those with low levels of sales.
- Introduction of government funding for the APVMA's activities in informing policy in accordance with the principle of the Cost Recovery Guidelines that costs not directly related to the provision of products or services should not be recovered.
- Maintenance of the APVMA's financial reserve to support financial viability in managing short term fluctuations in the level of activity.
- Regular monitoring and adjustment of fees and charges in line with changes in expenditure rather than automatic indexation.

3.1. Summary of Recommended Cost Recovery Framework

The following table outlines the cost recovery framework recommended by the Review, alongside details of the cost recovery model currently in place for each type of activity. The rationale for the recommended framework is described above with detailed explanations by activity type provided in section 4 of this report.

Activity	Current Model	Recommended Model
Registration and Approvals		
Product and Active-Constituent Registrations and Approvals		
Applications for product registration, approval of active constituents, major variations and minor changes requested by applicants	Application fee and balance by levy	An upfront application fee is charged based on the average cost of assessing an application of that type or module.
Minor changes required by the APVMA	No fee is charged to the applicants. Activity is funded by the annual fee	An upfront application fee is charged based on the average cost of assessing an application for minor changes.

Activity	Current Model	Recommended Model
Permits		
Permits for possession and export and extensions of export permits	Minor application fee of $350 and balance by levy	An upfront application fee is changed based on the average cost of assessing an application for a permit for possession and export. For permit extensions, an upfront application fee is changed based on the average cost of assessing an application for a permit extension.
Minor use permits and extensions of minor use permits	Minor application fee of $350 and balance by levy	An upfront application fee is charged as a small contribution to the cost of assessing a minor use permit or a permit extension, with most of the costs being recovered through a specific identifiable tiered annual flat levy that is charged on all registered products.
Emergency use permits and extensions of emergency use permits	No fee is charged to the applicants. Activity is funded by the levy	A specific tiered annual flat levy is charged on all registered products to recover the costs of assessing emergency use permits and permit extensions.
Research permits and extensions of research permits	Application fee and balance by levy	An upfront application fee is charged based on the average cost of assessing an application of that type or module. For permit extensions, an upfront application fee is charged based on the average cost of issuing an extension of the permit for each applicable module.
Miscellaneous permits and extensions of miscellaneous permits	Application fee and balance by levy	An upfront application fee is charged based on the average cost of assessing an application of that type or module. For permit extensions, an upfront application fee is charged based on the average cost of issuing an extension of the permit for each applicable module.
Application Advice		
Pre-application advice	Standard fee and hourly rate. A portion of the fee charged is rebated on submission of an application	An upfront standard fee is charged for each request for advice based on the average cost of administratively processing the request and issuing an estimate of the likely fee in providing the requested advice. An hourly rate is charged for conducting research, obtaining further information from the requestor and the provision of advice. The applicant would also be charged the hourly rate for any additional advice sought beyond the initial request. Where pre-application advice is sought in relation to an application that has a subsidised fee (being for a minor or emergency use permit), the upfront fee and hourly rate should be subsidised in a consistent manner. The fee charged is not rebated on submission of an application.
Other Market Activities		
Certificates of Export	Application fee	An upfront application fee is charged based on the average cost of assessing an application for Certificates of Export.
Consents to Import	No fee is charged to the applicants. Activity is funded by the annual fee	An upfront application fee is charged based on the average cost of assessing an application for Consents to Import.

Activity	Current Model	Recommended Model
Monitoring Ongoing Compliance with Regulations and Investigation and Enforcement		
Manufacturing Standards of Agvet Chemicals		
Compliance with standards for the manufacture of veterinary chemicals (such as the current MLS and Overseas GMP Scheme)	Specific categorised annual fees charged to manufacturers of veterinary medicines with an annual fee concession funded by industry	For Australian manufacturers of veterinary medicines, an upfront application fee is charged for a licence to manufacture based on the average cost of assessing an application. An additional specific categorised annual levy is charged based on average cost to confirm compliance for manufacturing processes differing in complexity. For any variations to licences, an additional fee is charged if the APVMA determines that an audit is required. This additional fee is based on the average cost of reviewing the audit. For veterinary medicines manufactured overseas, the local registrant of the product is required to pay a tiered annual flat levy based on the average cost to confirm compliance for manufacturing sites outside Australia.
Compliance with standards for the manufacture of agricultural chemicals (such as the current AgQA Scheme)	Activity is funded by the annual fee	A specific annual flat levy is charged on each registered agricultural chemical product.
Other Compliance Monitoring, Investigation and Enforcement Activities		
Regulation of the supply of particular products (such as the current HGP)	Specific flat annual fee charged to HGP suppliers	An upfront application fee is charged based on the average cost of assessing an application for a licence to supply a particular product. A flat tiered annual licence renewal levy charged to licence holders to recover the full cost of maintaining the scheme.
System for the public to provide feedback on agvet chemicals (such as the current AERP) and programs for the APVMA to conduct reviews of registered chemicals (such as the current Chemical Review Program) and undertake compliance and enforcement action	Levy	A specific tiered annual flat levy is charged on all registered products.
General Activities		
Website, annual report and corporate publications, consultative committees, presentations and seminars and the information publishing scheme	Levy	A specific tiered annual flat levy is charged on all registered products.
Informing policy (including Senate estimate hearings, Questions on Notice, Ministerial briefings)	Levy	Government appropriation
Research (i.e. Principal Scientists)	Levy with partial government appropriation	A specific tiered annual levy is charged on all registered products. The levy charged is offset by any government appropriation provided for specific research activities.

Other Recommendations

Recommendation 1

We recommend that applicants are offered a discount for upfront payment of a fee where they are eligible for payment in instalments but elect to pay upfront. This discount should reflect the cost of administering a more complex instalment payment scheme.

Recommendation 2

We recommend that the annual flat levy charged be comprised of separate identifiable fees for each type of activity in order to allow registrants to appreciate the proportion of costs recovered for each activity conducted by the APVMA.

Recommendation 3

As the recommended framework can result in a significant increase in the annual flat levies charged for a range of activities, we recommend that the levies be tiered based on the value of agvet chemical product sales during the preceding year.

For the current MLS, we recommend that the categorised annual fee be tiered based on the total notional wholesale value of chemical products manufactured during the preceding year as manufacturers (rather than registrants) are charged the annual levy.

Recommendation 4

We recommend that for any application withdrawal, the applicant is charged a proportion of the application fee based on the costs incurred by the APVMA in assessing the application prior to notification of the withdrawal.

Recommendation 5

The APVMA should monitor the level of non-compliance with requirements relating to consents to import through its compliance and enforcement processes. Should there be a significant increase in the level of non-compliance, the APVMA should conduct a detailed review to identify the root causes relating to the detected instances of non-compliance.

Recommendation 6

We recommend the continuation of the APVMA's reserve mechanism in order for the APVMA to maintain financial viability in managing short term fluctuations of its activity.

Recommendation 7

We recommend that the APVMA's fees are not subject to any automatic indexation.

3.2. General Mechanisms Applicable to Recommended Cost Recovery Framework

Payment of Application Fees by Instalment

The recommended cost recovery framework introduces full cost recovery for assessment of all application types, aside from those for minor and emergency use permits (or extensions of these permits). In order to promote innovation in the industry and encourage compliance with the Agvet Code, the recommended framework permits the payment of application fees in instalments where the total fee is above a threshold (of say $10,000). All applicants should be offered the option to make payments in instalments where the total fee for their application exceeds this threshold. For example, 40 per cent of the costs could be paid at the time of application with the remainder being due in three subsequent annual instalments, with a fee adjustment to cover the cost of administering the more complex approach and the APVMA's collection risk exposure due to instalment payments. This fee adjustment should be based on the average cost of administering the instalment payment arrangement. The collection risk for each of these application types can be initially estimated with

reference to the credit ratings of recent applicants, with regular adjustments made to reflect the level of uncollectable debt identified through administering the arrangements as part of CRIS processes.

As applicants electing to pay the full fee upfront would not incur the additional administrative costs for the instalment payment arrangements, they should be charged the application fee with no fee adjustment. For application fees below the threshold, the fee would be payable by the applicant in full at the time of application.

This threshold should be set at a level that allows for the APVMA to recover a significant portion of costs incurred in assessing applications during the year while minimising the impact on innovation in the agvet chemicals market.

The instalments should be uniform to simplify administrative processes and assist potential applicants in understanding the arrangement. For withdrawals of applications, payment by instalment should be permitted to recover the costs incurred by the APVMA prior to receiving notification of the withdrawal, if these costs exceed the threshold.

The instalments should not be subject to any annual indexation as the fee payable relates to costs incurred at the time of assessing the application.

The frequency of instalment payments and duration over which they are collected should be determined by balancing collection risk and administrative complexity due to the payment arrangement and the ability of smaller companies in making the payments. For example, if the threshold was set at $10,000, the APVMA would be able to receive fees upfront for most applications received. The majority of category applications submitted in 2011-12 were for categories with an assessment cost to the APVMA that was less than $10,000. For application fees above the threshold, funding would be required for the APVMA to continue operations in the initial years, until there is a steady flow of instalments from previous years' activities. Continued use of the APVMA's reserve mechanism would allow the APVMA to manage a degree of the volatility in activity levels from year to year. Significant under recovery that exceeds the capacity of the APVMA's financial reserve would need intervention

Tiered Annual Levies

The recommended framework includes annual levies for the recovery of costs incurred for a range of activities, including compliance monitoring, investigation, enforcement, general activities[14], MLS and GMP compliance, assessment of applications for emergency use permits and the majority of costs in the assessment of applications for minor use permits.

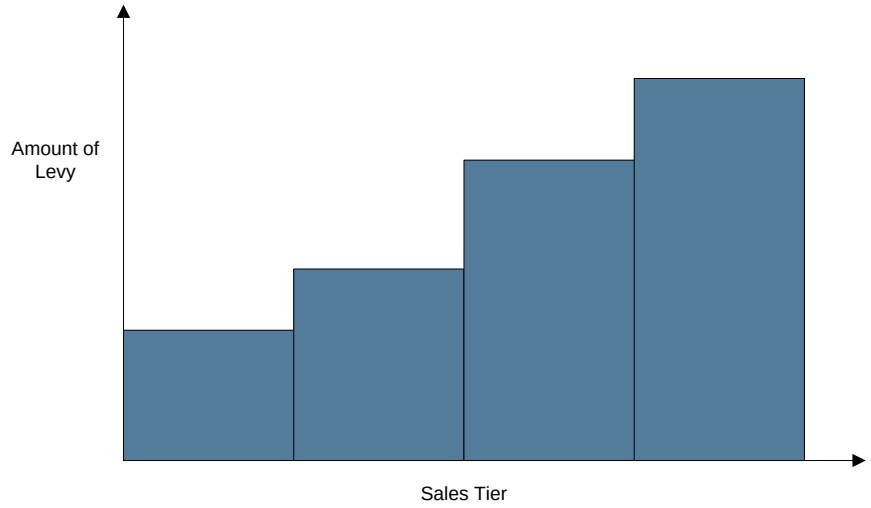
In order to support the continued supply of products with low levels of sales, and in particular niche products that are vital for Australia's primary industries, we recommend that the levies be tiered based on the value of the product's sales during the preceding year. This would be similar to the current sales-based levy charged by the APVMA in that it requires registrants of products with high sales revenue to subsidise amounts charged to registrants of products with little or no sales. However under the recommended model, the levy is capped and registrants are not able to maintain registration without payment of levies. This requires all registrants to make a contribution to the costs incurred by the APVMA but they would no longer be required to make payments that expand potentially indefinitely with increases in sales. This would also assist in clearing the register of outdated unused agvet chemicals.

As illustrated by the diagram below, all registered products would be charged annual levies based on the tier or level of sales revenue. All products falling within a particular tier will be required to pay the same levy amount for an activity. Registrants would be required to pay the levy amount for each applicable activity. For example, only some registrants would be required to pay an annual levy for the

[14] Specifically this relates to the recovery of costs incurred by the APVMA in monitoring compliance with manufacturing standards (such as the current GMP and AgQA Scheme), the APVMA's systems for the public to provide feedback on agvet chemicals (such as the current AERP), programs for the APVMA to conduct reviews of registered chemicals (such as the current Chemical Review Program) and undertake compliance and enforcement action, maintaining the APVMA's website and producing the annual report and corporate publication, participating in consultative committees, conducting presentations and seminars and the information publishing scheme and research activities.

AgQA Scheme. The levy applicable to each tier should set so that the level of cross subsidisation is the lowest amount required to ensure products with low or infrequent sales are not discouraged from maintaining registration.

Tiered Annual Flat Levy Structure for an Activity



Annual fees are also charged for the regulation of compliance with standards for manufacture for agvet chemicals. In order to encourage new manufacturers of agvet chemicals to enter into the market and support the production of niche products of agricultural or veterinary significance, we recommend the tiering of these annual levies in a manner that is consistent to the structure outlined above. Specifically, levies under the current Overseas GMP and AgQA Schemes can be tiered based on annual product sales as the levies are paid by registrants. As manufacturers (rather than registrants) are charged the annual levy under the current MLS, we recommend that the annual fee for Australian manufacturers of veterinary chemicals be tiered based on the total notional wholesale value of chemical products manufactured during the preceding year.

The number of tiers and thresholds for tiering the levy should be set at levels that distinguish smaller registrants or manufacturers who are unlikely to be able to afford payment of the full levy amount. For simplicity in administering the tiering mechanism, one set of tiers should be applied to all annual flat levies paid by registrants and one set of tiers should be applied to manufacturers.

3.3. Discussion

For the purposes of the Review, Protiviti identified, in line with the scope discussed in section 2.6, a number of matters as critical in assessing potential cost recovery models. The following sections provide further details on the rationale for our recommended cost recovery framework against these critical matters. Additional detailed analysis of the recommended cost recovery model for each activity type has been provided in section 4 of this report.

Compliance with the Cost Recovery Guidelines

The APVMA's cost recovery arrangements are required to be consistent with the Cost Recovery Guidelines with clear reasoning for any deviation from the principles of the Guidelines and subsequent Government authority.

The cost recovery framework recommended by the Review is broadly consistent with the Cost Recovery Guidelines as the majority of the APVMA's costs are recovered by charging a fee for service based on the average cost of conducting assessment activity. A fee based on the average cost of an activity may result in the under recovery of costs where the APVMA is required to expend more effort in completing the activity for an individual user. However a more precise cost recovery framework that charges users based on the individual cost of conducting an activity would be complex and inefficient to administer.

The recommended framework deviates from the Cost Recovery Guidelines principle of the direct user of a service paying for the service where it requires all product registrants to pay a flat annual levy for the majority of costs in assessing applications for minor and emergency use permits (including pre-application advice related to these permits). This principally relates to delivering specific policy objectives on enabling access to agvet chemicals. Minor use permits are intended to address market failure in accessing agvet chemicals for minor uses. The term minor use is defined as "a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use"[15]. Depending on the complexity and quality of the application submitted, the costs incurred in assessing applications for minor uses can amount to a similar cost to some applications for registration. Charging an application fee to recover the full cost would not align with the policy intent of minimising regulatory barriers for access to agvet chemicals, especially to those with low levels of sales. For emergency use permits, charging an application fee to recover the full cost of assessment and provision of pre-application advice can prevent users in submitting an application promptly. Reducing the cost barrier in applying for emergency use permits can minimise the likelihood of unapproved use of chemicals in response to an emergency. The timely use of an assessed chemical in response to an emergency could lessen damage to Australia's primary industries and ensure the safety of people, animals, crops and the environment.

The Cost Recovery Guidelines indicate that a levy may be used, where it is efficient to do so. The annual flat levy included in the recommended framework is a levy to recover the costs of compliance activities, information services and other general activities. Although the users of these services can include users of unregistered agvet chemicals or the general public, the need for the activities has been created by industry. Charging a direct fee for service would be impractical or inefficient for these activities. However the recommended cost recovery framework deviates from the Cost Recovery Guidelines where it recommends tiering of the flat annual levies charged for compliance monitoring, investigation, enforcement and general activities16. This tiering delivers on the policy objective of encouraging users to access agvet chemicals by supporting the continuity of supply of registered products with low levels of sales. Specifically, tiering of the annual flat levy mitigates some of the likely increases in the cost of maintaining registration for products with low levels of sales, which can support the continued supply of vital niche products required to support primary industry.

The Cost Recovery Guidelines state that "costs that are not directly related or integral to the provision of products or services (e.g. some policy and parliamentary servicing functions) should not be recovered." The activity conducted in informing policy is not directly related to the conduct of the APVMA's current programs. The industry as a whole is an indirect user of these services as informing policy is related to maintaining the social license that allows these products to be used in Australia. However the activities are conducted at the request of government, who is the primary user of the services.

The recommended cost recovery framework does not include automatic indexation of the APVMA's fees and charges, in accordance with principles of the Cost Recovery Guidelines. If the APVMA does not monitor and adjust fees and charges in line with changes in expenditure, this may result in the under recovery of costs for some activities. However automatic indexation could stifle the generation of efficiencies in the APVMA's processes.

The recommended cost recovery framework also does not subsidise the cost of assessing applications submitted by Australian government agencies. This is consistent with the Cost Recovery Guidelines, which indicate that charges between agencies should be set on the same basis for all applicants, regardless of whether they are Australian government agencies.

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[15] *Agricultural and Veterinary Code Regulations 1995*

[16] Specifically this relates to the recovery of costs incurred by the APVMA in monitoring compliance with manufacturing standards (such as the current GMP and AgQA Scheme), the APVMA's systems for the public to provide feedback on agvet chemicals (such as the current AERP), programs for the APVMA to conduct reviews of registered chemicals (such as the current Chemical Review Program) and undertake compliance and enforcement action, maintaining the APVMA's website and producing the annual report and corporate publication, participating in consultative committees, conducting presentations and seminars and the information publishing scheme and research activities.

Enable Access to Agvet Chemicals

As outlined in section 2.1 of this report, the agvet chemicals industry is comprised of a variety of companies that range in size. It is important to ensure that any change to the cost recovery framework does not stifle competition in the market by driving out smaller companies, who would find it difficult to afford upfront payments for full cost recovery of activities. In order to reduce the cost impact of application fees on industry, the recommended cost recovery framework allows for payment by instalment where the application fee exceeds a nominated threshold. Although applicants would still be required to pay an increased amount of application fees, this lets applicants spread the fee across several years. This could reduce the need for a significant increase in the cost of products for end users.

Use of annual flat levies to recover the costs of a number of activities may create difficulties for smaller companies, who may be forced to remove the product from market if they are unable to afford the levies. Tiering of annual flat levies on each registered product would mitigate some of the cost burden in maintaining registration for products with low levels of sales. This in turn will reduce the impact on continued supply of registered products to market.

The cost recovery framework subsidises the application fee and the provision of pre-application advice for minor and emergency use permits and permit extensions. This minimises cost barriers to accessing niche agvet chemicals.

Promote Innovation

The recommended framework recovers the full cost of assessing applications, which would increase the total fees paid by applicants. While this could stifle innovation in the agvet chemicals industry, several elements of the recommended framework promote the development of innovative products.

Specifically, for application fees exceeding the threshold, the recommended framework allows for the upfront application fee for product registration and research permits to remain similar to current levels. The remaining costs would then be recovered through instalment payments over several years. The option to pay the application fee in instalments will reduce the funds required upfront for registration of an innovative product and allows the registrant to pay instalments with cash generated from sales revenue.

In considering the development of innovative products, companies would also analyse the cost of maintaining registration. The recommended framework includes a tiered annual flat levy, which recovers a higher proportion of costs from products earning higher levels of revenue. This results in a lower cost of maintaining registration for products that have low levels of sales. This has the potential to encourage companies to develop innovative products as some of the risk in releasing a new product is taken on by registrants of products earning higher revenue.

For innovative products that are successful in the market, registrants would no longer be required to make uncapped levy payments that expand potentially indefinitely with increases in sales.

The subsidisation of minor and emergency use permit application fees can encourage users to seek permits for minor uses or in response to emergency situations. This can support niche markets and result in applicants seeking to use registered products for innovative off-label uses or the development of innovative unregistered products.

Encourage Compliance

The recommended framework recovers the cost of the APVMA's compliance monitoring and enforcement activities through tiered annual flat levies charged on all registered products. This allows for product registrants to appreciate the cost of compliance activity and may encourage the industry as a whole to comply with agvet chemicals legislation in an effort to reduce the levies for compliance activity.

The APVMA does not currently target compliance activity on products that may be of a higher risk of non-compliance. Since the NRS is focussed on toxicity risk mitigation (such that agvet chemicals are only registered or approved where no risks remain unmitigated), the APVMA is not able to differentiate products based on health risk exposure and by extension develop a simple cost structure for compliance activities relating to individual products. Nevertheless, some segments of the market

may be subject to more frequent and intensive reviews. For example, investigation and enforcement activities could be seen as being more important for products with lower levels of sales as these products have had less use and apparent issues may not yet have been identified. However the development and maintenance of a categorisation methodology would be complex. Additionally the APVMA would risk reputational damage if a serious compliance incident occurs involving a product that had previously been identified as being of a lower compliance risk.

While charging individual registrants a direct fee based on the actual costs of compliance activity for their products would encourage compliance, it would be complex for the APVMA to administer and difficult for registrants to forecast the fee. Additionally the APVMA is likely to encounter difficulties in recovering costs incurred in conducting compliance activity for unregistered products.

The subsidisation of the application fee for minor and emergency use permits may also minimise the barriers to seeking approval for the use of unregistered chemicals or the off-label use of registered chemicals, rather than using an agvet chemical in an unapproved manner.

Financial Sustainability of the APVMA

The recommended cost recovery framework supports the financial sustainability of the APVMA by matching cost recovery with closer drivers of activity within the APVMA. During the 2011-12 financial year, 72 per cent of the costs incurred by the APVMA related to the assessment of applications for registration. The framework recovers these costs through an application fee as this activity is driven by the number of applications the APVMA receives for registration. Additionally the upfront application fee for categories and modules with an assessment cost below a given threshold allows for the APVMA to be able to collect the associated fees prior to incurring expenditure in processing the application.

For applications with a cost above the threshold, a mechanism would be needed to provide funding for assessing applications in the initial years. A mechanism like the existing reserve would ensure the APVMA is able to meet its expenses in processing these applications during the period over which the instalment payments are collected. The reserve can be used to manage short term fluctuations in activity without Government intervention, with the APVMA making adjustments to its cost base to reflect long term trends. Risk of non-payment of instalments could be reduced by requiring that payments be made as they fall due to ensure continued registration. Nonetheless government intervention may be required where large numbers of registrants become unable to make payments.

Although the annual flat levy included within the recommended framework is not closely linked to the cost of compliance, monitoring and general activities performed by the APVMA, it provides stability over the recovery of these expenses. While there may be some fluctuation dependent on the number and sales revenue of registered products, the fees collected would not vary as significantly as with the sales based levy within the current cost recovery framework. This will give the APVMA more certainty over the recovery of these costs. As all registrants are required to pay the annual flat levies, the recommended cost recovery framework could also incentivise registrants to only seek to continue registration for products that are in use, which would assist in clearing the register of outdated unused agvet chemicals.

The APVMA relies on the sales levy (where a surplus is available – which is not always the case), or drawing on the APVMA's reserve, to cover revenue gaps arising due to any increases of expenses between CRIS cycles. Although the Cost Recovery Guidelines do not specify a minimum time period for a CRIS cycle, some agencies deal with the issue of cost growth between CRIS cycles by introducing an additional indexation of fees and charges.

The current cost recovery framework does not allow for automatic indexation of fees and charges. The Review recommends the continuation of this arrangement with the intent that the APVMA monitor activities and seek to adjust fees and charges in line with changes in expenditure. These reviews can be conducted outside a formal CRIS review point and could be used to consider the need for a CRIS. In developing a CRIS, this approach will allow for the APVMA to highlight where efficiencies have been generated to offset rising costs when seeking fee increases.

Transparency of Spending

The Cost Recovery Guidelines indicate that the cost recovery framework adopted by agencies should be transparent. The recommended framework for assessing applications for registration provides for the recovery of the full assessment cost through an application fee. This increases the transparency of the effort expended by the APVMA in conducting this activity. It allows for the applicant to appreciate the cost incurred by the APVMA for the assessment and could be used as a mechanism to identify opportunities to gain efficiencies in the assessment process.

The annual flat levy recommended for recovering costs associated with compliance monitoring and general activities is not as transparent as a direct fee for service, particularly with the inclusion of tiering based on sales revenue. This means that it could be difficult for each product registrant to understand the effort expended by the APVMA in providing these services. However it is recommended that a separate annual flat levy be charged for each activity type, which would allow registrants to easily identify and appreciate the proportion of costs recovered for each activity. Mechanisms outside the cost recovery framework could also be used to increase transparency of spending on activities recovered through an annual flat levy. For example, the United Kingdom Chemicals Regulation Directorate (UK CRD) indicated that they issue reports outlining the manner in which funds raised from the industry are used to deliver outputs for the industry. Detailed reporting of the performance of compliance monitoring and general activities conducted by the APVMA would assist the industry in understanding the outputs generated as a result of the APVMA's work. This is particularly important as a number of the submissions received on the Review consultation paper indicated that industry stakeholders had a poor understanding of the effort expended by the APVMA in providing some services.

Submissions on First Principles Review Consultation Paper

Stakeholders highlighted a range of general concerns with respect to the overall cost recovery framework, including:

- A preference for costs to remain at the same level or decrease as an increase in costs would increase the burden industry bodies will be required to bear;
- Some stakeholders indicated a preference to move away from a levy-based cost recovery framework, explaining that the current levy promotes inefficiency, acts as a tax and the role of the cost recovery scheme is not to act as a mechanism for industry support;
- Some submissions indicated a preference of the continuation of a sales based levy but with a minimum levy and the removal of the levy cap;
- Some of the submissions explained that an annual fee to maintain registration would be preferred as the cost of maintaining registration does not change based on the amount sold;
- Some stakeholders did not support the continuation of the current annual registration fee as it was seen to be a source of general funding for the APVMA; and
- While some stakeholders were not supportive of automatic indexation on the basis that it could lead to inefficiencies within the APVMA, others supported indexation based on CPI or a set rate per annum.

Although outside the scope of the Review, a number of submissions suggested changes in the regulatory model, including a move to a risk based model, recognition of overseas data packages, separation of regulation of agricultural and veterinary chemicals and separation of regulation of pool and spa products. Stakeholders indicated that the permits system should also be reviewed to consider the types of permits offered, the length of time taken in issuing a permit and the effort expended by the APVMA in assessing permit applications. Several submissions also suggested the completion of an efficiency review of the APVMA's activities, with one stakeholder highlighting that industry cannot determine whether fees paid and assessment times are fair and reasonable because the APVMA has a monopoly in performing its services.

4. Analysis of Recommended Models

The following sections detail our recommended cost recovery model for each group of activities conducted the APVMA, along with the rationale for our recommendation.

Our consultation paper[17] provides detailed analysis of the advantages and disadvantages of a range of cost recovery mechanisms. Submissions received during the public consultation process have been considered in recommending a cost recovery model, with a summary of the key issues raised from submissions provided under our analysis of the relevant activity type below.

4.1. Registration and Approvals

4.1.1. Assessments of Applications for Product Registration, Approval of Active Constituents, Major Variations and Minor Changes Requested by Applicants

Background

All agvet chemicals supplied, sold, distributed and used in Australia must be approved and registered by the APVMA. This includes all agvet chemical active constituents, products and product labels[18]. In order to obtain approval, an application for registration must be submitted to the APVMA. The APVMA assesses each application through analysis of the data package submitted as part of the application and conducts a rigorous and independent evaluation of the safety and efficacy of the chemical. Product labels must also provide adequate instructions for safe and effective use of the product. Additionally registrants are required to submit applications to seek the APVMA's approval prior to making any variations to a registered product or previously approved label. In 2011-12, the APVMA incurred costs of approximately $19 million in processing 2,451 applications for registration of agvet chemicals and major variations[19].

Recommended Model

We recommend that an application fee be established to recover the full cost of assessing applications. The application fee will be standard for each category and module type, based on the average assessment cost for that category or module. The average cost would be estimated through an activity based costing model similar to that currently used by the APVMA.

Discussion

The current cost recovery framework comprises a fee payable on application for registration (reflecting 40 per cent of the full cost of processing the application) with a sales-based levy to meet the balance of costs. Revenue collected from the levy also funded other means of users accessing agvet chemicals, including the issue of minor use permits. Some stakeholders, particularly producers of niche products, have argued that any increase in up-front costs will adversely affect commercial decisions to register products. However the use of a sales-based levy results in the registrants of products with high sales paying amounts exceeding the original cost of their application's assessment. These registrants subsidise the cost of applications for products with low sales volumes, which may not be subject to levies commensurate to the cost of assessing their applications.

An application fee for the full cost of assessment would closely align costs with the user of the application. The applicant seeking a registration or approval is the party that triggers the need for the APVMA to incur the costs of assessment. The Cost Recovery Guidelines indicate that recovery through a fee would be appropriate where the applicant receives an exclusive capturable commercial benefit. This is achieved by the data protection rights applicable for a number of years for innovative product and active constituent registrations. This requires for the registrant to provide explicit consent before any subsequent applicants can leverage data used for the initial registration.

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[17] A copy of this consultation paper can be found at http://www.daff.gov.au/__data/assets/word_doc/0009/2354535/apvma-consultation-paper.doc

[18] In certain circumstances, agvet chemicals may be approved for use under a permit. Further details of these permits have been provided in the sections that follow.

[19] APVMA Activity-Based Cost Model 2011-12

Although there may be some over or under recovery of costs within categories or modules, the fee will be reflective of the average time and resources incurred in providing a service under the category or module. This model clearly shows how the fee derives from the average effort expended by the APVMA in assessing an application. This transparency would allow users to appreciate the true cost of the services provided by the APVMA and may serve as a driver of efficiency in processing applications.

The SWG recommended the APVMA's current framework as high upfront application fees were considered to cause suppliers to decide against developing new agvet chemical products, which could stifle innovation. Based on the information collated by the APVMA's systems, we were unable to determine the number of innovative products submitted for registration or the size of the company submitting an application for innovative products.

Nonetheless, some stakeholders may not be able to afford the increased application fee in the proposed model, which may reduce innovation in the industry. Although the proposed model would result in increased application fees, the option of payment by instalment would increase affordability by easing cash flow requirements for applicants through spreading the costs over a period. While being transparent, this model provides applicants the opportunity to pay instalments with cash generated from sales revenue.

A standard fee also gives potential applicants certainty over costs when considering whether to register a product. It may also support companies' decisions to invest in research activities for innovative products as it would be easier to determine the full cost of developing a product to release to market.

As registrants would not be required to pay an ongoing uncapped sales-based levy to recover application assessment costs, registrants would be positioned to reduce the price of high-selling products. If registrants pass a portion of this saving to end users, it could improve access to agvet chemicals.

The APVMA's reliance on a sales-based levy under its current framework can cause a financial sustainability issue for the agency if insufficient funding is available for continued operation through its financial reserve. The APVMA's cost base is driven by the pace of regulatory activity, including the number of applications received. However this is not directly linked to the activity of the agvet chemicals industry. For example, a drought or exchange rate fluctuation may result in a decrease in demand for, and sale of, agvet products. While this reduces the APVMA's income from the levy, it does not necessarily follow that there will be fewer applications or lower levels of regulatory activity.

The type and number of applications received is a closer driver of the APVMA's activity. Consequently, the use of an application fee to recover the full assessment cost can minimise the over or under recovery of expenditure.

Alternative Mechanisms to Promote Innovative or Niche Products

It is noted that mechanisms outside the cost recovery framework could be used to promote the registration of innovative or niche products. Depending on policy considerations following the Review, this could include government-funded grant schemes targeted towards vital niche products required to support primary industry. This could be driven by both registrants and end user industries. An example of such a mechanism is the work of existing Research and Development Corporations in funding data generation in support of some minor use permits.

Submissions on First Principles Review Consultation Paper

No stakeholders indicated government appropriation as being appropriate for these activities. There was no clear consensus in how costs of applications should be recovered by the APVMA, however:

- Most stakeholders did not support the full upfront recovery of costs, highlighting the financial barrier to entry for new entrants to the market and the potential to stifle innovation in product development;
- Some stakeholders indicated that a reduction in the cost of the application fee would not greatly impact innovation as the main cost of registering a product for release to market is the cost of developing the chemical and the regulatory data required for registration;

- Several stakeholders supported the continuation of the current cost recovery model at the target rate of 40 per cent fee and 60 per cent levy as the sales based levy was viewed as an 'equitable' means of recouping regulation costs;
- Stakeholders that did not support the recovery of costs incurred in assessing applications through a levy preferred the option of having predictable instalment payments (with a preference for the upfront application fee to remain at current levels and the recovery of the remainder of costs through payments deferred over two to five years); however they highlighted that under a deferred payment model, the economic risk is transferred to the APVMA where the APVMA may not be able to recover the full cost; and
- Some stakeholders did not support the reduction of fees for new products or active constituents, while others supported the provision of a discount for these applications.

Alternate options for the recovery of costs incurred in assessing applications for registration were raised in stakeholder submissions, including a mechanism to foster innovation through requiring registrants to register say two new products per annum, or pay an annual levy.

Although beyond the scope of the Review, we noted that some stakeholders suggested amendments to the registration process through conducting risk-based tiered assessments to accommodate low risk categories of products, and the increased reliance on overseas data. A number of stakeholders suggested a review of the efficiency of the APVMA's processes in assessing applications for minor changes made at the request of registrants. Stakeholders also highlighted that it may be more appropriate for specific publicly funded programs to be established to support smaller registrants and local innovators seeking registration in Australia.

4.1.2. Minor Changes Required by the APVMA

Background

Minor changes generally occur due to the introduction of technical standards by government authorities or international bodies, as a function of the health and safety standards required for continuing in the market. In 2011-12, 171 applications were lodged for minor changes with an assessment cost of $2,561,718[20].

Changes requested to satisfy the needs of the registrant have been considered in section 4.4.1 of this report.

Recommended Model

We recommend that an application fee of the full assessment cost is paid by the applicant at the time of application. This fee should be based on the average cost of processing an application for a minor change.

Discussion

Charging an application fee for the full assessment cost ensures that the costs are borne by the applicant, who uses the service, would align with the principles of the Cost Recovery Guidelines. Although it may be considered inequitable to charge for changes made at the request of the APVMA, this would not differ from the principle that applicants are required to comply with technical standards in registering a product. The recommended model for recovering the costs of minor changes required by the APVMA is consistent with the model for applications for registration of products.

Processing of applications for minor changes is largely administrative in nature. A fee based on average cost would generally be reflective of the effort expended by the APVMA in processing the application. This would also improve the transparency of the cost recovery arrangements as applicants would be able to appreciate the cost of processing a minor change application. This increased transparency can also drive the generation of efficiencies in processing applications for minor changes.

As applicants are required to pay a fee for each application, this cost recovery model would minimise cross subsidisation that can occur if specific types of products or industries require frequent minor

[20] APVMA Activity-Based Cost Model 2011-12

changes. As the APVMA's costs in processing applications for minor changes are driven by the number of applications received, an application fee would closely reflect the driver of the activity. This would assist in ensuring the financial viability of the APVMA.

Although charging an application fee may discourage registrants from making required changes, instances of non-compliance with the Agvet Code would be detected through the investigation and enforcement activity undertaken by the APVMA and the States and Territories.

Submissions on First Principles Review Consultation Paper

There was limited stakeholder feedback on how costs of minor changes should be recovered by the APVMA. Stakeholders commenting on the recovery of cost of applications for minor changes indicated government appropriation as being appropriate where changes are due to government decisions or interventions to amend technical standards. Some stakeholders expressed concern on the cost impost for registrants under a full cost recovery model, particularly where they have multiple products requiring a minor change. For example, one stakeholder indicated that based on the current cost of assessing an application for minor changes, a registrant would be required to pay fees in excess of $40,000 to comply.

4.1.3. Permits for Possession and Export and Extensions of Possession and Export Permits

Background

Permits for possession and export allow for a person, usually the applicant, to possess and supply an unregistered chemical to persons outside Australia. In 2011-12, 31 of these permits were lodged with an assessment cost of $82,738. Over this period, application fees of $10,850 were collected for the permits issued[21].

Recommended Model

We recommend an upfront application fee of the full assessment cost be paid by the applicant. As issuing permits for possession and export is largely an administrative process, this should be a standard fee based on the average cost of assessing a permit for possession and export. The fee for extensions of permits for possession and export should also be a standard fee based on the average cost of issuing an extension of the permits.

Discussion

This model would align well with the principles of the Cost Recovery Guidelines as it allows for the costs of issuing a permit for possession and export to be borne by the applicant, who uses the permit. Additionally charging an application fee for the full assessment cost provides transparency as to the cost of providing the service. As the APVMA's activities in issuing permits for possession and export are driven by the number of applications received, recovery of the full cost by way of an application fee would align closely with the drivers of cost. Charging an upfront application fee also assists with ensuring the financial sustainability of the APVMA as the fee is received prior to the APVMA incurring costs in assessing the application.

Despite these clear benefits of the recommended model, an increase in the application fee for possession and export permits could result in a higher level of non-compliance or it may act as a barrier to exporting unregistered chemicals to overseas markets, discouraging the manufacture of agvet chemicals locally for export. Although the fee may be significant to small local manufacturers, the introduction of this fee is likely to have minimal impact on larger manufacturers as the fee to recover the full cost of issuing these permits would be approximately $2,702[22].

Alternative Mechanisms to Promote Local Manufacture of Agvet Chemicals for Export

It is noted that mechanisms outside the cost recovery framework could be used to promote the local manufacture of agvet chemicals for export. Depending on policy considerations following the Review, this could include government-funded grant schemes to support the local manufacturing industry, particularly the activities of small local manufacturers. Any mechanisms introduced for the

[21] APVMA Activity-Based Cost Model 2011-12
[22] This fee is an estimate based on the APVMA Activity-Based Cost Model 2011-12

development of innovative agvet chemicals may also have the effect of promoting the manufacture of products and active constituents in Australia.

Submissions on First Principles Review Consultation Paper

There was very limited stakeholder feedback on the cost recovery model for permits for possession and export. One stakeholder submission highlighted that these permits are used both for unregistered products manufactured in Australia for export as well as imported products passing through Australia en route to overseas locations. Consequently any changes in the cost recovery arrangements would impact the local manufacturing industry.

Although beyond the scope of the Review, we noted that stakeholders suggested a review of the efficiency of the APVMA's processes in assessing applications for permits for possession and export.

4.1.4. Minor Use Permits and Extensions of Minor Use Permits

Background

Minor use permits are issued to allow for the minor use of an unregistered product or active constituent or the unapproved (or off-label) use of a registered product. The costs incurred in assessing a minor use permit depend on the type and number of assessment modules applicable to the specific application. In 2011-12, 154 minor use permits were issued with an assessment cost of $411,023. Over this period, application fees of $53,900 were collected[23]. The APVMA also received $135,000 of administered funding to be contributed towards the administration of the program[24].

Recommended Model

We recommend that the activity should be funded through an application fee that covers a small portion of the assessment cost with the remainder being recovered through an annual flat levy paid for all registered products. 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.

The recovery of costs incurred in assessing applications for extensions of minor use permits should also be based on this principle, whereby a small portion of the assessment cost is recovered through an application fee. For simplicity in administering the cost recovery model, we would recommend that the fee charged for extensions should be consistent with the quantum of the fee charged for minor use permits.

The APVMA would be required to continue to assess whether applications for minor use permits meet specified criteria to be eligible for a minor use permit. Where the applicant is a Commonwealth, State or Territory government agency, the agency should also be required to pay the application fee.

Discussion

Minor use permits are intended to address market failure in accessing agvet chemicals for minor uses. The term minor use is defined as "a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use"[25].

Depending on the complexity and quality of the application submitted, the costs incurred in assessing applications for minor uses can amount to a similar cost to some applications for registration. The recovery of the full cost of a minor use permit application assessment from applicants would result in a significant increase in fee, which can deter users from accessing agvet chemicals for minor use, particularly when coupled with the cost of generating data required for the application. Although the Cost Recovery Guidelines indicate that costs should generally be recovered from the user of the service, a model that recovers the full cost of assessment from the minor use permit applicant would

[23] APVMA Activity-Based Cost Model 2011-12
[24] APVMA Annual Report 2011-12
[25] *Agricultural and Veterinary Code Regulations 1995*

not align with the intent of minor use program in encouraging users to access agvet chemicals. Consequently the recommended model subsidises the application fee for minor use permits.

The low cost barrier in applying for minor use permits under the recommended model will continue to encourage users to obtain minor use permits for innovative new products or uses of existing products. Use of agvet chemicals in accordance with minor use permit requirements can provide confidence in the safety and efficacy of the agvet chemical. Consequently, products approved for use under minor use permits will have increased levels of sales, resulting in higher revenue for the products' registrants. Recovery of a portion of the cost through an annual flat levy on all registered products would result in a low cost being applied to each individual product[26], which will mean that any cost increases passed on to end users are likely to be minimal. This minimal increase in individual product price and the subsidised application fee can encourage users of niche products, that are vital for producing outputs but have low sales volumes, to seek minor use permits. Encouraging users to access agvet chemicals, particularly for innovative uses of agvet chemicals, can assist in improving the competiveness of Australia's primary industries.

The application fee charged under the recommended cost recovery model recognises the use derived from the applicant as the primary user of the permit. Consistent with the Cost Recovery Guidelines, the recommended model recovers a portion of the cost of issuing minor use permits through a flat levy as other users are able to free ride on all or aspects of the approval of the first applicant. This ability to free ride arises from the lack of data protection rights for minor use permits, which allows subsequent applicants seeking an identical (or highly similar) minor use permit to leverage on the technical assessment conducted on the original permit application. Further the flat levy included in the recommended model recognises that permits issued where the applicant is a representative body for a group of users are generally not restricted to any one individual or group[27].

Recovery of the majority of the costs of issuing a minor use permit through an annual flat levy also reflects the increase in sales of registered products approved for use under a minor use permit. The recommended cost recovery model ensures that the product registrant pays a portion of the cost of issuing a minor use permit.

Although the recovery of the majority of costs through an annual flat levy would result in an over or under recovery of costs each year, the impact of this on the APVMA's financial sustainability can be reduced through accurate forecasting of the number of minor use permits processed. Continued use of the APVMA's reserve mechanism would allow the APVMA to manage a degree of the volatility in the costs recovered from year to year. An adjustment to the annual flat levy can then be made through the CRIS process.

Although the permit applicant may not be able to appreciate the full cost of assessment of a minor use permit, the specific, identifiable annual flat levy charged on all registered products provides some transparency to the industry on costs incurred by the APVMA. This may drive the generation of efficiencies in processing minor use permit applications.

This recommended model is consistent with the Cost Recovery Guidelines in that the fee charged is set on the same basis for all applicants, regardless of whether they are Australian government agencies.

Alternative Mechanisms to Promote Innovative or Niche Products

While the payment of a small portion of the cost of issuing minor use permits may assist some applicants in funding for a minor use permit, the main cost incurred by applicants can be on data generation required to address regulatory requirements, which can be significant. For example, one submission received on the consultation paper for the Review indicated that the data generation costs to meet regulatory requirements for a minor use permit totalled $22,000. Consequently, even a full

[26] Although extending the annual fee to unregistered products approved for use under a minor use permit would provide a broader base for recovering costs, it is rare for the APVMA to approve an unregistered product under a minor use permit

[27] The APVMA issues permits in this manner in order to prevent processing multiple duplicate minor use permits for each individual user.

subsidisation of cost of minor use permit applications may not significantly lower the cost barrier to obtaining approval of a minor use.

Mechanisms outside of the cost recovery framework, such as expedited assessments of registration applications, are likely to be more effective in addressing such barriers. Additional cost efficiencies in issuing permits could be generated if multiple growers or grower groups sought approval for a range of off-label uses of an agvet chemical through one application rather than submitting a number of separate applications relating to the same agvet chemical.

The Better Regulation of Agricultural Chemicals and Veterinary Medicines reforms included changes (from July 2014) to encourage registration by permitting other parties aside from the registrant (with the registrant's agreement), to register for the on-label use of products and active constituents. Attempts to reduce barriers to accessing minor use permits could interfere with policy efforts such as these reforms, which are aimed at encouraging registration of new products or uses rather than off-label use.

These issues are largely outside the scope of the Review.

Submissions on First Principles Review Consultation Paper

There was a significant amount of stakeholder feedback in relation to minor use permits but no consensus on the cost recovery methodology could be reached. Key points raised by stakeholders included:

- Most stakeholders agreed that an upfront application fee to recover the full cost of assessment was not feasible and would create adverse impacts. Several stakeholders pointed to qualitative studies undertaken on the impact of minor use schemes, which indicated (at minimum) a 13:1 benefit from the scheme;
- Many stakeholders suggested the current cost recovery model be maintained with a fee structure that is likely to be affordable for applicants;
- Many stakeholders suggested government appropriation as being applicable as the benefits of minor use permits extend beyond the applicant and the permits are often used by government, and in general for trade, animal welfare and public health reasons;
- Several stakeholders identified that subsequent applicants are able to free-ride on the initial minor use permit application as there is no data protection or any 'commercially capturable benefit'. Additionally some submissions indicated that as their members would not be in a position to fund individual applications, the permits would not have a 'commercially capturable benefit' that is restricted to a single applicant. One stakeholder pointed to the cost recovery arrangements of Food Standards Australia New Zealand, which does not recover the cost of applications where the applicant does not have an exclusive commercially capturable benefit. One stakeholder highlighted that this could be addressed through charging a high application cost, which would create a barrier for subsequent applicants seeking to free-ride on the initial application; and
- One stakeholder highlighted that product registrants may be incentivised to register for an on-label use of a product approved for used under a minor use permit as they are able to appreciate the increase in sales over the life of the permit.

Submissions offered alternative models including the following:

- An additional levy for products approved for use through a minor use permit, the funds from which can be quarantined for use in supporting the scheme;
- Government appropriation (or a reduced label extension fee) for the transfer of all minor use permits to label registration after a set period of time;
- A points-based credit system for registrants who transfer minor use to on-label uses; the points from which can be used for the acceleration of registrations; and
- Fee waivers for permit applications made by not-for-profit organisations.

Stakeholders indicated that it is unrealistic to expect to incentivise participation in the agvet chemicals market through the regulatory environment alone. Some stakeholders supported the use of mechanisms outside the cost recovery model to assist users in applying for minor use permits. Stakeholders highlighted that the cost of data generation required for permit applications can be significant.

4.1.5. Emergency Use Permits and Extensions of Emergency Use Permits

Background

Emergency use permits allow for emergency use of an unregistered agvet chemical or the off-label use of a product in unforeseen circumstances. The applicant may be any person or organisation, including individual growers or farmers, grower associations, government departments, government institutions, veterinary surgeons and manufacturers or suppliers of agvet products. In some instances, unregistered products are allowed for manufacture and supply under emergency use permits. In 2011-12, 57 of these permits were issued with an assessment cost of $152,132[28].

Recommended Model

We recommend that the assessment costs for emergency use permits are recovered through an annual flat levy charged on each registered product. Consequently applicants would not be required to pay for emergency use permits. The APVMA would be required to continue to assess whether applications for emergency use permits meet specified criteria to be eligible for an emergency use permit.

Discussion

The recommended model encourages users to promptly seek an emergency permit for the manufacture of an unregistered agvet chemical for emergency use or off-label use of a product in emergency circumstances. Even a minor application fee can cause delays in the submission of an application in an emergency, where it can be vital to access required agvet chemicals on a timely basis. Reducing the cost barrier in applying for emergency use permits can minimise the impact of an emergency on Australia's agriculture, fisheries, forestry and food industries. This would support the maintenance of a regulatory system that is able to promptly respond to emergencies. Additionally this may encourage the development of innovative products or new uses of registered products to respond to emergency situations.

The Guidelines state that a levy is more appropriate than a fee-for-service when others are able to free ride on the approval of the original applicant. Although the primary user of the emergency use permit is the applicant (who may be a representative body for a group of users), the annual flat levy included in the recommended model is consistent with this principle of the Cost Recovery Guidelines. Others are able to free ride on emergency use permits as there are no data protection rights for emergency use permits and the APVMA can issue general emergency use permits that are not restricted to particular users.

By being applicable to all registered products[29], this model minimises the cost impact on individual products.

The continuation of the APVMA's assessment of whether the applicant is seeking an emergency use permit to respond to an emergency would prevent users from accessing the permits in other urgent situations.

Although the permit applicant would not be able to appreciate the full cost of assessment of an emergency use permit, the specific, identifiable annual flat levy charged on all registered products provides some transparency to the industry on costs incurred by the APVMA.

As with the cost recovery model recommended for minor use permits, recovery of the majority of costs through an annual flat levy would result in an over or under recovery of costs each year. Continued use of the APVMA's reserve mechanism would allow the APVMA to manage a degree of the volatility in activity levels from year to year. This can be especially beneficial for the recovery of costs in assessing applications for emergency use permits as emergency situations can be inherently difficult to predict.

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[28] APVMA Activity-Based Cost Model 2011-12

[29] Although extending the annual fee to unregistered products approved for use under an emergency use permit would provide a broader base for recovering costs, it is rare for the APVMA to approve an unregistered product under an emergency use permit.

Submissions on First Principles Review Consultation Paper

A significant amount of feedback was provided by stakeholders in relation to emergency use permits. Stakeholders highlighted that an application fee to recover the full assessment cost would be significant for most applicants. They explained that this could be a barrier to promptly implementing management practices, which would impede the effective management of pests and diseases. One stakeholder provided an example of a recent emergency use permit, which would cost $30,186 if full cost recovery was applicable to it. In general, many stakeholders suggested government appropriation as being a valid approach, noting that there should be no disincentive for governments to take the lead in eradiation and control campaigns which provide benefits to industry and the wider community. However some stakeholders indicated a preference for the current arrangement for cost recovery of emergency use permits to remain, explaining that it is difficult to identify which groups gain the benefit from controlling environmental pests and diseases in emergencies. As with minor use permits, they highlighted that there are no exclusive commercially capturable benefits or data protection rights granted to the applicant. Stakeholders highlighted that emergency use permits are generally sought on behalf of an industry or on a cross-industry basis.

Alternate options for the recovery of costs incurred in assessing emergency use permits were raised in stakeholder submissions, including the suggestion that state and territories could contribute to a fund based on a per capita basis.

4.1.6. Research Permits and Extensions of Research Permits

BackgroundThe APVMA predominantly assesses applications for research permits under category 23. This category is also used for applications for permits for possession or supply of unregistered agvet chemicals for other miscellaneous purposes. Section 4.1.7 of this report provides details of the recommended cost recovery model for these permits.

Applications for research permits are modular and the cost of the application can vary depending on the complexity of the applicable modules. Data must be provided when a technical assessment is required. Data requirements, the fee payable and timeframe depend on which of the modules are required for assessment of a particular permit application.

The APVMA issued 135 research and miscellaneous permits in 2011-12 with a cost of $877,945[30].

Recommended Model

We recommend an upfront application fee of the full cost of assessing the application. This fee should be modular with the fee reflecting the average cost in assessing each applicable module. The fee for extensions of research permits should also be modular, based on the average cost of issuing an extension of the permit for each applicable module.

Under this model, all applicants, including Australian government agencies, would be required to pay the application fee.

Discussion

The recommended cost recovery model would align well with the principles of the Cost Recovery Guidelines that indicate the costs of assessment should be borne by the applicant, who uses the permit. While there can be flow on impacts from research and development of an agvet chemical, the primary user of the research permit is the applicant. This model is transparent in linking the application fee with the effort expended by the APVMA in assessing the application. This increased transparency can be a key means of improving efficiency in processing applications. This would also allow users to appreciate the true cost of the services provided by the APVMA.

The upfront recovery of the full cost of assessment can create a significant cost impost in conducting research activities, which may discourage organisations from developing innovative agvet chemicals. In order to mitigate some of these impacts, the recommended model includes an option to pay the application fee by instalments. This would increase affordability by easing cash flow requirements for applicants through spreading the costs over a period. This would allow for research organisations to arrange funding over a number of years rather than seeking an upfront payment of the full application fee.

[30] These figures are based on the APVMA Activity-Based Cost Model 2011-12.

Payment of application fees for research permits by instalment could expose the APVMA to a higher collection risk. Unlike product registrations, for which registrants could fund instalment payments through sales of the registered product, research organisations may find it difficult to make instalment payments. This is because, in general, research and development activities only become commercially viable after a number of years. The recommended model allows for any increase in collection risk to be included in the fee adjustment made for opting to pay by instalment.

Although the recommended model does not subsidise the application fee, if the applicant seeks to register a product, active constituent or product use following the issue of a research permit, the applicant would be able seek a modular assessment in order to reflect reliance on aspects of the risk assessment the APVMA conducted in issuing the research permit[31]. This would reduce the cost to the research organisation in registering the agvet chemical and prevent the APVMA from over recovering the cost of assessing these applications.

This model assists in ensuring the APVMA's financial sustainability as the APVMA would be able to receive the application fee before it incurs expenditure in conducting the activity. As the APVMA's expenditure in assessing applications is driven by the number and type of research permit applications received, use of an application fee to recover the full cost of assessing the applicable modules can minimise the over or under recovery of expenditure.

The recommended model is consistent with the principle of the Cost Recovery Guidelines, which indicates that charges between agencies should be set on the same basis for Australian government agencies and other applicants.

Alternative Mechanisms to Promote Research and Development of Innovative Products

As with applications for product registration, it may be more effective for research permits to be subsidised through government-funded grant schemes rather than through the APVMA's cost recovery model. Applying broad subsidisation to all applications for research permits through a cost recovery model does not allow government to promote specific issues or areas of research. Use of mechanisms such as grant schemes can be targeted towards specific priorities for research activities.

Submissions on First Principles Review Consultation Paper

There were a limited number of stakeholders who provided feedback in relation to research permits. Some submissions indicated support for the current arrangements in order to ensure application fees do not act as a deterrent in conducting research. One stakeholder advocated that where the research project has a less clearly defined beneficiary or is in the public interest, a research grant (through government appropriation) should apply. Another stakeholder indicated that the cost of research permits should be recovered through fees charged for the registration of agvet chemicals.

4.1.7. Miscellaneous Permits

Background

The APVMA assesses applications for permits for possession or supply of unregistered agvet chemicals for miscellaneous purposes that would otherwise be an offence against the Agvet Code. Although applications for miscellaneous permits are submitted under category 23, the category is predominately used for applications for research permits. The APVMA issued 135 research and miscellaneous permits in 2011-12 with a cost of $877,945[32].

Recommended Model

We recommend that the costs of assessing applications for miscellaneous permits are recovered using a model that is consistent with that recommended in section 4.1.1 of this report. This would mean that an upfront application fee is charged based the full cost of assessing the application. This fee should be modular with the fee reflecting the average cost in assessing each applicable module.

[31] The reliance placed on modules in registering a product or active constituent would depend on the extent to which the risk mitigation strategies of a research permit can extend to the product or active constituent for which registration is sought.
[32] These figures are based on the APVMA Activity-Based Cost Model 2011-12.

The fee for extensions of miscellaneous permits should also be modular, based on the average cost of issuing an extension of the permit for each applicable module.

Discussion

Section 4.1.1 provides the rationale for this recommended model for miscellaneous permits.

4.1.8. Pre-Application Advice

Background

From 1 July 2014, the APVMA will no longer provide unlimited free pre-application assistance (the cost of which was previously incorporated into the cost recovery arrangements for application assessment costs). Specifically, potential applicants requesting pre-application advice will be charged an initial fee of $350, reflecting two cost units for staff to review the request, conduct research and attend meetings. Additional cost units will be added to the initial fee, based on the time taken to prepare and provide the advice.

If the applicant proceeds to lodge an application, a rebate will be given. This rebate is provided on the basis that the pre-application advice will improve the quality of the application submitted. The amount of the rebate differs by application category and has been determined according to the complexity of the advice likely to be sought for particular categories. Any rebates that are not fully offset by a reduction in costs in assessing applications would be factored into the average cost of assessing applications.

Recommended Model

We recommend an upfront standard fee is charged for each request for pre-application advice. This should be based on the average cost of administratively processing a request and issuing an estimate of the likely fee in providing the requested advice. An hourly rate is charged for conducting research, obtaining further information from the requestor and the provision of advice. The hourly rate should also be charged for any further advice sought beyond the initial request.

We recommend the removal of the rebate for pre-application advice.

Where pre-application advice is sought in relation to an application that has a subsidised fee, the upfront fee and hourly rate should be subsidised in a consistent manner. Specifically, as the cost of assessing applications for emergency use permits is fully recovered through the annual flat levy charged on each registered product, the provision of pre-application advice relation to emergency use permits should also be recovered through this annual flat levy. For minor use permit applications, which are partially recovered through the annual flat levy, the upfront fee and hourly rate should be set at a level that balances the ability for the APVMA to recover a portion of the cost of providing pre-application advice while not acting as a significant disincentive for users to seek a minor use permit.

Discussion

This model aligns well with many elements of the Cost Recovery Guidelines. It recovers costs from the requestor of pre-application advice, who creates the need for the service. The model deviates from the Cost Recovery Guidelines in subsidising the cost of pre-application advice for minor and emergency use permits in order to support the intent of these programs. Further details of the recommended model for minor and emergency use permits are provided in section 4.1.4 and 4.1.5 of this report.

Submission of applications that do not meet the APVMA's requirements would result in the rejection of the application, leading to registrations being more costly and taking a longer duration for these applicants. Seeking pre-application advice allows the applicant to ensure a high quality application is submitted through better understanding the APVMA's requirements, which would assist in expediting the application assessment. As pre-application advice is aimed at ensuring applications are of an acceptable quality for the APVMA to conduct its assessment, obtaining pre-application advice would not mean that the APVMA is able to take less time in the assessment conducted. Consequently the recommended model does not include a rebate for obtaining pre-application advice.

Prior to 1 July 2014, the APVMA's application assessment cost included the provision of advice in remediating issues identified with applications. From 1 July 2014, the cost of assessing an application

only provides for very limited guidance to be given on the remediation of issues with an adjustment made for any applications that have an assessment effort exceeding the fee charged net of the rebate. By separating pre-application advice from the application assessment cost and removing the rebate, the recommended model reduces the cross-subsidisation that can occur where the fee charged (net of any rebates) is not reflective of the assessment effort. Consequently the recommended model improves the transparency of the effort expended by the APVMA in providing advice. This mechanism would allow users to appreciate the true cost of the advice provided by the APVMA. Further the separation of these costs would result in a reduction in the application fee, which could assist in encouraging registration of agvet chemicals, particularly for experienced applicants who are unlikely to require pre-application advice.

The recommended model allows for the flexibility required in providing pre-application advice, which can differ depending on the level of input and the complexity of advice sought by the applicant. As a result, this model minimises the over or under recovery of costs incurred in providing pre-application advice. Provided that the hourly rate charged is reflective of the cost incurred when providing pre-application advice, this cost recovery model would assist in ensuring the financial sustainability of the APVMA. This is due to the fees charged being reflective of the drivers of cost incurred by the APVMA in providing pre-application advice.

In order to assist the requestor of the advice to decide whether they would like to continue with the request, the APVMA should keep the requestor informed of the likely cost in providing pre-application advice. Although the recommended model may be viewed by some users as being complex, these estimates will assist users in understanding the fee. It will also assist users in ensuring sufficient funds are available for the advice sought, which will be particularly beneficial for smaller companies, grower groups or research institutions that may have very limited funding available.

The recommended model could lead to a perception that the APVMA is taking unnecessary time to provide advice to raise revenue. Although it can be difficult for the APVMA to provide comparative data to illustrate the efficient use of time in providing advice, the provision of estimates of the likely cost can assist the requestor in determining whether they are getting value for money for the service.

The fee charged under this cost recovery model can be complex, costly and difficult to administer. However the removal of the fee rebate (which would have required for the APVMA to track and apply rebates over a number of years) simplifies the administrative arrangements for pre-application advice. Additionally the consistency in subsidisation of the upfront fee and hourly rate can simplify administrative arrangements and assist users in understanding the likely cost.

Submissions on First Principles Review Consultation Paper

There were a limited number of stakeholders providing feedback in relation to pre-application advice costs with no clear consensus as to the preferred model of cost recovery. Several stakeholders supported recovery from applicants on a user pays basis, including the cost recovery model to be introduced from 1 July 2014. Stakeholders emphasized that the fee set must reflect the true cost for this service and provide incentive for applicants to seek this advice. However some stakeholders indicated support for an annual fee being charged for all registered products. They highlighted that charging an upfront fee for pre-application advice would discourage users from accessing this service.

One stakeholder indicated that the service could have the added benefit of reducing the timeframes required for the APVMA to register products and active constituents, however they highlighted that this benefit would be limited by the APVMA refusing to provide technical assessment services under this service. We note that this is outside the scope of the Review.

4.2. Other Market Activities

4.2.1. Certificates of Export

Background

Certificates of export are issued by the APVMA and contain information about an agvet chemical or manufacturing site, which is often required by overseas countries before accepting agvet products

from Australia. In 2011-12, revenue from 405 certificates of export totalled $51,365. Over this period, the costs of providing the activity were $79,407[33].

Recommended Model

We recommend the continuation of the current cost recovery model for certificates of export, whereby an application fee is charged reflecting the full cost of issuing a certificate. This fee should be based on the average cost of processing an application for a certificate of export.

Discussion

The user of the certificate of export is the exporter, who is required to pay the application fee under this cost recovery model. Charging an application fee to recover the full cost of issuing a certificate is transparent and allows the applicant to appreciate the effort expended by the APVMA in conducting the activity. This approach is consistent with the principles of the Cost Recovery Guidelines. Further a standard fee based on the average cost of processing an application is appropriate as the processes conducted by the APVMA in issuing a certificate are largely administrative and do not vary greatly for each application.

As the overall cost of issuing certificates of export are driven by the number of applications received, recovering the full cost of issuing a certificate through an application fee minimises the likelihood of over or under recovery of cost. The upfront application fee results in the APVMA obtaining a fee prior to incurring the cost of issuing the certificate. This would assist in ensuring the financial sustainability of the APVMA.

Despite these clear benefits of the recommended model, the cost impost of obtaining a certificate of export may discourage exporters from engaging in trade in overseas markets, which may impact Australia's international trade. Alternatively, this may result in the export of agvet chemicals without the certification required by overseas regulators. Although the fee may be significant to small local manufacturers, this impact is likely to be minimal as the cost per certificate would be approximately $196[34]. As mentioned in section 4.1.3 of this report, mechanisms outside the cost recovery framework can also be used to promote the local manufacture of agvet chemicals for export.

Submissions on First Principles Review Consultation Paper

There was a limited feedback provided in relation to certificates of exports with some stakeholders indicating support for full cost recovery from applicants.

Although largely outside the scope of the Review, we noted that stakeholders indicated that multiple products should be issued on the one certificate at a reduced rate per product where appropriate.

4.2.2. Consents to Import

Background

Consents to import are granted to allow the import of an unregistered agvet product or unapproved active constituent into Australia, usually under limited circumstances. For example, consent may be granted to allow a veterinary surgeon to import an unregistered veterinary medicine for use on an animal under their direct care or for use in research trials. In 2011-12, the APVMA incurred $291,405 of expenditure in assessing 617 applications for consents to import[35].

Recommended Model

We recommend the recovery of this activity through an upfront one-off application fee reflecting the full assessment cost. This fee should be based on the average cost of issuing a consent to import.

Where a consent to import is associated with a permit application, the consent to import will be processed within the permit application assessment. Consequently a separate application fee for a consent to import should not be charged.

[33] APVMA Activity-Based Cost Model 2011-12
[34] This fee is an estimate based on the APVMA Activity-Based Cost Model 2011-12
[35] APVMA Activity-Based Cost Model 2011-12

Discussion

The recommended model is consistent with the principles of the Cost Recovery Guidelines. Similarly to certificates of export, the user of the consent to import is the applicant, who is required to pay the application fee under this cost recovery model. Charging an application fee based on the full cost of issuing a certificate is transparent.

As the effort taken by the APVMA in issuing a consent does not vary greatly for each application, a standard fee based on the average cost of processing an application is appropriate. As with certificates of export, charging an application fee closely matches the driver of cost for the APVMA in issuing consents to import.

Despite these benefits, charging an application fee for the full cost of issuing a consent to import can prevent users from accessing required agvet chemicals or increase the likelihood of illegal importation. The charge imposed may be a significant cost barrier, which could impact community goodwill (such as from significant cost increases for treating companion animals) and social licence for the regulatory system. This could potentially result in the use of high risk agvet chemicals in a manner that could impact the safety of people, animals, crops and the environment.

The APVMA should monitor the level of non-compliance with requirements relating to consents to import through its compliance and enforcement processes. Should there be a significant increase in the level of non-compliance, the APVMA should conduct a detailed review to identify the root causes relating to the detected instances of non-compliance. The outcomes of this review could include adjustments to public education mechanisms or consideration of subsidisation of the application fee through government appropriation.

Alternative Mechanisms to Promote Access to Agvet Chemicals

While subsidisation of the fee for consents to import through the APVMA's cost recovery framework can promote access to agvet chemicals for specific uses, there may be more efficient means for users accessing these chemicals. Policy initiatives such as grant funding schemes can be used to direct government funding to targeted purposes like research trials.

Submissions on First Principles Review Consultation Paper

There was a limited stakeholder feedback in relation to certificates to import. Stakeholders did not support the continuation of cost recovery through the annual registration fee. They instead supported full cost recovery from applicants.

Although largely outside the scope of the Review, we noted that stakeholders indicated that multiple products should be issued on the one certificate at a reduced rate per product where appropriate.

4.3. Monitoring Compliance with Regulations, Investigation and Enforcement

4.3.1. Compliance with Standards for Veterinary Chemicals Manufacture

Background

The APVMA regulates the manufacture of veterinary chemicals against standards, which currently manifests though the GMP. The Agvet Code provides that veterinary products manufactured in Australia must be manufactured in premises that are GMP compliant. GMP compliance is assessed through two schemes: the MLS for Australian manufacturers and the Overseas GMP Scheme for products manufactured overseas and imported into Australia. The Overseas GMP Scheme ensures registrants of veterinary products manufactured overseas maintain evidence that products are manufactured in accordance with a standard at least equivalent to the APVMA's requirements.

For the MLS, the main costs incurred by the APVMA are the initial assessment of the licence application and audit report to decide whether a licence should be issued and consideration of subsequent audit reports. In 2011-12, APVMA staff requested evidence of compliance with GMP for

155 imported products and APVMA authorised auditors conducted 24 audits of foreign manufacturers. The cost of this activity in 2011-12 was $1.46 million[36].

The current cost recovery model for the MLS also provides for an the annual fee concession of 50 per cent if the holder of the licence provides evidence to the APVMA that the total notional wholesale value of the chemical products is less than $50,000 in the preceding financial year.

Recommended Model

We recommend the continuation of most aspects of the cost recovery approach introduced on 1 July 2013. Specifically, for the regulation of the manufacture of veterinary products in Australia, an upfront application fee should be charged based on the average cost of assessing an application for a licence to manufacture. The cost of monitoring compliance with manufacturing standards[37] should be recovered through a set of annual levies charged to licence holders based on the average annual cost of this activity per license holder for a category. These categories reflect the intensity of effort required to confirm compliance for manufacturing processes of differing complexity. A fee based on the average cost of assessing any required audits should also be charged for a variation to a licence, if the APVMA determines an audit is required.

For the regulation of veterinary products manufactured overseas, registrants of the veterinary products should be charged an annual flat levy to recover the costs of ensuring compliance with manufacturing standards. This fee should be charged for each manufacturing site outside Australia, regardless of the number of products manufactured at the site.

We recommend that the tiered annual levy mechanism be used for the MLS and Overseas GMP Scheme instead of the current annual fee concession. As mentioned in section 3.2, the annual fee for the MLS should be tiered based on the total notional wholesale value of chemical products manufactured during the preceding year as manufacturers (rather than registrants) are charged the annual levy. The levies under the Overseas GMP Scheme can be tiered based on annual product sales as the levies are paid by registrants. The number of tiers and thresholds for tiering should be set at levels that distinguish smaller manufacturers who are unlikely to be able to afford payment of the full levy amount.

Discussion

This cost recovery model closely aligns the cost of issuing licences and monitoring of compliance with licence conditions by charging manufacturers (where veterinary products are manufactured in Australia) and registrants (where veterinary products are manufactured overseas). These manufacturers and registrants create the need for maintaining a compliance system for veterinary medicines. This approach is consistent with the principles of the Cost Recovery Guidelines as costs are recovered from the users of the services who are a narrow and identifiable group. Further the cost recovery model is transparent in allowing users to appreciate the effort expended by the APVMA in issuing a licence and conducting monitoring activities.

Through the use of a categorised annual flat levy for recovering the ongoing costs of running the MLS and an annual levy on registrants using the Overseas GMP Scheme, this model closely matches fees charged with cost drivers in conducting monitoring activities within the APVMA, which minimises the over or under recovery of costs. Although some cross-subsidisation of costs would occur where individual manufacturers or registrants require additional monitoring activity in a given year, charging the annual levies based on the average cost of the activities provides certainty of costs. Further the initial application fee charged for manufacturing licences under the MLS allows the APVMA to collect the fee prior to incurring costs in assessing applications. This assists in ensuring the financial sustainability of the APVMA.

[36] APVMA Cost Recovery Impact Statement 2013 – 2015

[37] Monitoring activities undertaken include timely conduct and closure of all audits for Australian-based manufacturers, preparing pre-audit information for auditors, reviewing audit reports, addressing disputes, answering manufacturer queries, updating licenses for routine changes (such as changes to personnel), and where necessary initiating compliance and enforcement action.

Recovery of the full cost of this activity from Australian manufacturers or importers of veterinary products may result in companies being less willing to invest in manufacturing a product for sale in Australia if they are uncertain that the product will yield an adequate return to cover these ongoing licence costs. The higher risk may not be acceptable for smaller companies, who may withdraw from the market. The tiered annual levy for the MLS and Overseas GMP Scheme included within the recommended cost recovery model will increase the affordability of the levy for smaller companies. Although this is a deviation from the Cost Recovery Guidelines as it will result in some manufacturing licence holders paying inflated annual MLS and Overseas GMP Scheme levies, the tiering mechanism is intended to further the policy objective of encouraging new manufacturers or registrants to enter into the market and provide fee relief for smaller manufacturers of veterinary products, including niche medicines of veterinary significance that are not being manufactured on a commercial scale.

Alternative Mechanisms to Encouraging Access to Veterinary Medicines

There may be more mechanisms outside the cost recovery framework that are more efficient in encouraging access to these chemicals. Policy initiatives such as grant funding schemes can be used to direct government funding to targeted purposes like the promotion of local manufacture of veterinary medicines (and in particular, to encourage new manufacturers to enter the market) or to support the need to produce small quantities of very important products in the case of a disease outbreak or disruption to the normal supply of a veterinary medicine.

Submissions on First Principles Review Consultation Paper

There was a limited number of stakeholder feedback in relation to GMP costs, however:

- Some stakeholders support the current arrangements, noting full cost of the MLS and Overseas GMP Scheme is recovered through several categories; and
- One stakeholder suggested recovering more costs from overseas manufacturers, citing that many overseas regulators recover costs through charging overseas manufacturers for the privilege of participating in their market. Local manufacturing can then be encouraged through discounts in registrations and fees.

Stakeholders indicated support for a concession of annual GMP fees. Although determination of the quantum of fees and thresholds was outside the scope of the Review, we noted that some stakeholders indicated that the GMP annual fee concession threshold of $50,000 is too low and a financial barrier for small manufacturers. They noted that a more appropriate threshold would be $500,000.

4.3.2. Compliance with Standards for Agricultural Chemical Manufacture

Background

The APVMA regulates the manufacture of agricultural chemicals against standards, which currently manifests though the AgQA Scheme. Through the Scheme, the APVMA ensures all agricultural active constituents, and ultimately products sold in Australia, are manufactured at authorised sites and that the active constituents and products supplied meet relevant standards. In 2011-12, the total costs of this activity were $163,921[38], however the costs of the AgQA may increase in future years where there is an increased level of activity.

Recommended Model

We recommend that an annual flat levy is paid by the registrant of each agricultural chemical product. This fee should be based on the average cost of conducting activities to regulate the manufacture of agricultural chemicals.

Discussion

This cost recovery model targets the annual flat levy to registrants of agricultural chemical products. Consistent with the principles of the Cost Recovery Guidelines, this model closely aligns costs in regulating the manufacture of agricultural chemicals to those who create the need for the service.

[38] APVMA Cost Recovery Impact Statement 2013 – 2015

Although the use of a flat levy is simple to administer and for registrants to understand, there may be over recovery of costs from some manufacturers or registrants and under recovery from others. This is because the costs for the APVMA in conducting activities will vary between individual manufacturers or registrants of agricultural chemicals, yet all would pay the same fee under this cost recovery model.

Although a cost recovery model similar to that recommended for the regulation of manufacture of veterinary chemicals would be able to more closely match fees paid to the users of the service, the current legislation does not provide for a licensing model for the manufacture of agricultural chemicals. Should the regulation of agricultural chemicals move to a licensing model, the use of a cost recovery model consistent with that described in section 4.3.1 of this report would allow for closer alignment of costs to users of the service.

Although this cost recovery model will be more transparent to stakeholders as to the true cost of the activities conducted by the APVMA in regulating the manufacture of agricultural chemicals, it would also increase the annual flat levy paid by manufacturers and registrants of agricultural chemicals. This could act as a barrier for companies conducting research and developing innovative products for manufacture and release to the market. However the increased annual flat levy paid by manufacturers or registrants of agricultural chemicals would be reflected by a decrease in fees paid by manufacturers or registrants of veterinary medicines.

Submissions on First Principles Review Consultation Paper

There were a limited number of stakeholders providing feedback in relation to AgQA Scheme. Although outside the scope of the Review, one stakeholder suggested the removal of the AgQA Scheme altogether. Another stakeholder commented that there appeared to be no reason for the lack of a full GMP Scheme for agricultural chemicals.

4.3.3. Regulation of Supply of Particular Products

Background

The APVMA can regulate the supply of particular products to facilitate access to an overseas market. The APVMA currently imposes additional regulations on those who use HGPs through the HGP Scheme. It requires all sellers and suppliers of HGPs to have a valid notification number, which is issued by the APVMA and renewed annually. As at 30 June 2012, there were 291 APVMA-authorised suppliers of hormonal growth products. In 2011-12, the total costs for this activity were $95,006[39], however the cost of the HGP Scheme may increase in future years where there is an increased level of activity.

Recommended Model

We recommend that the cost of assessing new applications to be authorised suppliers of particular products should be recovered through an application fee to recover the full cost of assessment. The application fee should be based on the average cost incurred by the APVMA in assessing an application for a licence to supply the product. A flat annual renewal fee for licences should also be charged, which should reflect the average cost of the effort expended by the APVMA.

Discussion

This cost recovery model aligns with the principles of the Cost Recovery Guidelines, which state that agencies should generally design cost recovery arrangements so that costs are recovered from specific users of services. As the process for assessing applications for HGP licences is largely administrative, use of an application fee based on the average cost of issuing a licence ensures the fee charged is reflective of the effort expended by the APVMA. This prevents the cross-subsidisation of costs in issuing individual licences.

This model is simple to administer and transparently informs licence holders of the costs of maintaining the system. As the fee charged for applications and renewals closely matches the drivers of cost incurred by the APVMA, this model supports the financial sustainability of the APVMA.

[39] APVMA Cost Recovery Impact Statement 2013 – 2015

The separation of the application fee and annual renewal fee minimises cross-subsidisation between costs incurred in issuing licences and conducting ongoing monitoring activity. As the effort taken in ensuring compliance does not vary significantly for each licence holder, the recommended model closely matches the costs incurred by the APVMA to individual licence holders. Although the separation of the fees for the issue and renewal of licences can result in an increase in the application fee paid, it would be offset by a reduction of the ongoing fee paid for maintenance of HGP licences.

Submissions on First Principles Review Consultation Paper

There was a very limited stakeholder feedback in relation to HGP Scheme. One stakeholder indicated support for the current cost recovery arrangement in place.

4.3.4. Feedback Mechanisms, Reviews, Compliance and Enforcement

Background

The APVMA ensures chemicals approved for sale and use in Australia can continue to be used safely and effectively. There are a number of mechanisms for the APVMA to become of potential concerns about agvet chemicals. The APVMA can consider information on adverse experiences received, conduct assessments of registered agvet chemicals and deal with concerns through enforcement activities.

The AERP is the main mechanism for the APVMA to receive and consider stakeholder and public feedback on adverse experiences relating to the use of agvet chemicals. The AERP provides the APVMA with feedback about the quality, safety and efficacy of agvet chemicals in the field.

The Chemical Review Program conducts comprehensive reviews of registered agvet chemicals where the APVMA has concerns about the adequacy of the basis of an existing approval. This includes assessments to determine what the hazards and risks of an agvet chemical are, as well as risk mitigation that would need to be applied in order for it to be satisfied of the safety, efficacy and trade criteria. These reviews may be triggered by activity conducted under the AERP or through other sources of information that may raise concerns.

In 2011-12, the total costs for these programs were $2.5 million[40].

The APVMA also assesses and investigates claims that agvet chemicals may not be compliant with Australia's agvet chemicals legislation. The APVMA also audits market authorisations, conducts market surveillance and monitors chemical production in Australia. In 2011-12 the cost incurred in conducting this activity totalled $2.1 million[41].

Recommended Model

We recommend that the costs of conducting the feedback, review and compliance and enforcement programs are recovered through a specific annual flat levy charged on all registered products. This fee would be based on the average cost of conducting these activities.

Discussion

Although the APVMA's current mechanisms for receiving feedback on adverse experiences with agvet chemicals, performing reviews of agvet chemicals and conducting compliance and enforcement activities differ, they have been considered jointly in this section as they have broad similarities as to the manner in which cost recovery should occur.

The APVMA's review, compliance and enforcement activities consider both registered and unregistered agvet chemicals. Although the recommended model recovers the cost of these activities is recovered solely from product registrants, the industry as a whole creates the need for a regulated market that provides users with access to effective and safe agvet chemicals for use. The Cost Recovery Guidelines state that agencies should generally seek to recover costs from those who

[40] APVMA Cost Recovery Impact Statement 2013 – 2015
[41] APVMA Cost Recovery Impact Statement 2013 – 2015

create the need for regulation. Recovery of the cost of these programs through a fee on all registered products would result in closer alignment with the users of the service.

Under this model, the cost is shared equally among all product registrants. Allocation of cost across all registered products can make it unaffordable for smaller companies to maintain registration, who may be forced to remove products from market. Although this model would be easy for the APVMA to administer and for registrants to understand the levy payable, it allows for less transparency as to the effort expended by the APVMA, particularly where there is little visibility of the APVMA's activities.

While charging a direct fee for the APVMA to conduct a review activity would increase transparency and minimise the over or under recovery of costs, it can be problematic to identify who should pay the direct fee, particularly for grandfathered off-patent actives. As the selection of agvet chemicals for review is outside the control of the registrants, it would be difficult for registrants to anticipate the cost of a direct fee. Such a fee for investigations could raise concerns that reviews are being initiated as a revenue raising activity targeting individual stakeholders. An annual flat levy gives registrants a level of certainty over the costs in maintaining registration.

Use of a Risk-Based Cost Recovery Model for Compliance and Enforcement Activities

Some stakeholders have argued that some product types are of a higher risk of non-compliance. For example, it could be considered that certain products (either through the level of exposure or inherent compliance risks) drive more of the APVMA's costs of these programs. Submissions in response to the Review consultation paper indicated an industry preference to move to a cost recovery model that tiers an annual fee based on the risk of non-compliance with agvet chemical legislation.

Although such a model may be able to reduce the level of cross-subsidisation, the application of an approach that categorises fees based on the risk of non-compliance would result in a highly complex model. There would be a need to categorise products according to the risk of non-compliance for that product or registrant in conjunction with the risks from non-compliance for the product. It is likely to be extremely difficult and costly to determine which products or types of products are at higher risk from non-compliance. Further by defining which products are considered to be of higher risk, the APVMA could damage the products' reputation which may lead to dispute with registrants. The APVMA may also risk reputational damage should a serious compliance incident occur involving a product that had previously been identified as being of a lower compliance risk. It is unlikely that there will be any clear drivers of high risk or consistent causes of issues in products. It is instead likely that the issues causing one product to be a higher risk of non-compliance would vary considerably depending on a range of complexities. As a result, there may be resistance by some registrants on how the risk levels are defined and used. This approach would not be consistent with the principles of the Cost Recovery Guidelines, which state that costs should generally be recovered where it is efficient and effective to do so. Consequently the Review has not recommended the use of a risk-based model for the recovery of costs associated with the APVMA's compliance and enforcement activities.

Submissions on First Principles Review Consultation Paper

There were a significant number of stakeholders providing feedback in relation to AERP, Chemical Review and enforcement activities. Most stakeholders viewed these activities as being conducted for public good, indicating that it should be funded by government appropriation. Stakeholders highlighted that unregistered products potentially pose a risk to the general community and registrants choosing to comply with requirements should not be required to fund for enforcement activities in relation to unregistered products.

Some stakeholders suggested that it should be funded by annual fees differentiated based on the risk of non-compliance or level of monitoring activity performed by the APVMA. Stakeholders explained that there are many categories products that are of low risk and consequently all products should not be charged the same cost for monitoring. One stakeholder suggested that the Poisons Schedule be used as a means of tiering products for this purpose.

Some of the submissions indicated that a sales based levy would be an appropriate proxy for charging fees for these activities, explaining that products with higher sales have a higher risk of potential problems. However others indicated that higher sales volumes do not reflect higher risks. They highlighted that product hazard and sales volumes are not close proxies for drivers of review and compliance activities.

One stakeholder expressed preference for charging individual annual fees based on the previous year's actual compliance costs as it would incentivise registrants to comply.

4.4. General Activities

4.4.1. Website, Annual Report and Corporate Publications, Consultative Committees, Presentations, Seminars and the Information Publishing Scheme

Background

The APVMA is required to maintain a website, develop annual reports and corporate publications, represent itself on consultative committees, conduct presentations and seminars and implement the information publishing scheme. The APVMA incurred an estimated $436,934 of expenditure in conducting these activities during the 2011-12 year[42].

Recommended Model

We recommend that the costs of conducting these activities should be recovered through a specific annual flat levy charged on all registered products. This fee would be based on the average total cost of the activities. In order to do so, the APVMA would be required to cost these activities through an activity-based costing model.

Discussion

The recommended model recovers the costs of these activities through an annual flat levy, which is simple for the APVMA to administer and for registrants to understand. Further the separate identification of an annual flat levy for the activity type will allow for registrants to better appreciate the effort expended by the APVMA in providing these services. This transparency can be used to drive efficiency in the manner in which the APVMA conducts these activities.

Charging a flat annual levy, rather than a direct fee for service, would encourage users to access required information. This would result in a greater number of users being informed of key regulatory changes or processes, which would support government policy in making regulatory information freely available, where possible. In the long run, this would also result in the APVMA incurring less expenditure explaining changes or processes to individual applicants.

A cost recovery model that charges a direct fee for services provided to identifiable individuals would align closely with a number of the principles of the Cost Recovery Guidelines. However the fees collected from these activities are likely to be minimal, particularly in light of the additional administrative cost of monitoring and collecting a myriad of minor fees. Consequently this would not be consistent with the Cost Recovery Guidelines principle that costs should be recovered where it is efficient and effective to do so.

An annual flat levy may act as a cost barrier for registrants such as small or start-up companies. However, as the fee is allocated across a broad base (being all registrants), it is unlikely to be large. Based on the number of registered products as at 30 June 2011 and the estimated costs incurred during the 2011-12 year, the levy charged could be as small as $15 per registered product.

Submissions on First Principles Review Consultation Paper

Most stakeholders provided feedback that these activities should not be subject to cost recovery, but rather that they be funded through government appropriation. One stakeholder suggested that the cost of these activities be recovered through an annual fee.

4.4.2. Informing Policy

Background

The APVMA is required to undertake activity to inform policy. This includes activities such as participating in and responding to Senate estimate hearings, taking questions on notice and responding to and preparing Ministerial briefings; all of which are part of the required functions of a government regulator. It also involves, under the NRS regulatory partnership arrangement, briefings

[42] This an estimation of the cost of conducting this activity, which has been included as an overhead and allocated across the APVMA's pre and post-market activities.

and discussions with State and Territory governments. The APVMA incurred an estimated $299,279 of expenditure in conducting these activities during the 2011-12 year[43].

Recommended Model

We recommend that this activity be funded through government appropriation.

Discussion

The Cost Recovery Guidelines state that costs that are not directly related to the provision of services should not be recovered. The activity conducted relates to informing policy, it is not directly related to the conduct of the APVMA's current regulatory programs. Our consultation during the Review revealed that the Australian Fisheries Management Authority receives government funding for its policy support activities on the basis that public policy and legislation benefits the community at large. This would suggest that the activity conducted by the APVMA in informing policy should be taxpayer funded. Additionally, the Australian Sports Anti-Doping Authority, Food Standards Australia New Zealand, the Australian Fisheries Management Authority, the UK CRD, the New Zealand Environment Protection Authority and the New Zealand Ministry for Primary Industries receive government funding for the provision of policy support.

The recommended arrangement aligns with the principle of the Cost Recovery Guidelines that indicates that costs should be recovered from the user of the service. The activities performed by the APVMA in informing policy are conducted at the request of government, who is the primary user of the services. The industry as a whole is an indirect user of these services as informing policy is related to maintaining the social license that allows for these products to be used in Australia. These services performed ultimately underpin future improvements and reforms to the regulatory system and could conceivably be conducted by the Department of Agriculture. If this were to occur, the activities would be funded by government appropriation.

Government appropriation would be simpler to administer for the APVMA, transparent and would allow for government to appreciate the effort expended by the APVMA in providing these services. This transparency will position Government to seek to ensure costs efficiencies are gained in the provision of these services. The recommended approach can ensure sufficient funds are available for activities to be conducted in informing policy.

Submissions on First Principles Review Consultation Paper

Most stakeholders provided commentary on the APVMA's activities in informing policy, expressing that these activities are conducted for public good. They indicated that the activity should be funded by government appropriation.

4.4.3. Research

Background

The APVMA conducts research for information purposes, including the consideration of regulation of emerging technologies. This is largely conducted by the Principal Scientists in order to maintain a system that is able to effectively regulate emerging technologies. This activity is currently partly funded by one-off funding for research projects that are supported by one or more agencies. For example, in 2011-12, the Department of Innovation, Industry, Science & Research partially funded research into the regulation of nanotechnology as the agency has partial policy responsibility for assisting industry in preparing for the advantages and disadvantages of technology change. The cost of this activity in 2011-12 was estimated at $600,000[44].

Recommended Model

We recommend that the costs of conducting this activity should be recovered through a specific annual flat levy charged on all registered products. This fee would be based on the average total cost

[43] This an estimation of the cost of conducting this activity, which has been included as an overhead and allocated across the APVMA's pre and post-market activities.
[44] This an estimation of the cost of conducting this activity, which has been included as an overhead and allocated across the APVMA's pre and post-market activities.

of the activity. In order to do so, the APVMA would be required to cost these activities through an activity-based costing model.

The cost to be recovered would be offset by any funding received from agencies for specific research projects. This would be conducted through regular reviews as part of the CRIS process. Any short term fluctuations should be managed through the APVMA's reserve mechanism.

Discussion

This cost recovery model would align with the principle in the Cost Recovery Guidelines which indicates that costs should be recovered from those who create the need for regulation. The industry creates the need for a safe and effective agvet chemicals market in Australia. The outcomes of these research activities can result in improvements to the regulation of emerging technologies. This can ensure that the regulatory activity in Australia is abreast of technology changes. Ultimately, it will allow registrants to seek approval of innovative agvet chemicals, which can assist in ensuring the industry remains competitive with international suppliers.

Although the allocation of the cost of this activity to all product registrants would add to the cost of maintaining registration, based on the number of registered products as at 30 June 2011 and the estimated costs incurred during the 2011-12 year, the levy could be as small as $56 per registered product. This is unlikely to have a significant impact on continued supply to market or the development of innovative products for release to market.

Charging a specific annual flat levy improves the transparency of the APVMA's spending in conducting research activities. Although it is simple to administer, recovery by way of an annual flat levy is likely to result in the over or under recovery of costs because the APVMA's costs in conducting research are not directly related to the number of registered products. As research activity can be driven by a range of factors (which change over time), a more complex model that tiers costs based on those who create the most need for the activity was not considered justifiable.

Submissions on First Principles Review Consultation Paper

A number of stakeholders commented on the recovery of costs of research activities. Stakeholders viewed these activities as being conducted for public good as the APVMA would conduct research to develop new skills and increase its knowledge of new technologies. They therefore indicated that the costs of the activity should be funded by government appropriation. One stakeholder supported an annual fee on the basis that the APVMA would ensure that research was conducted for all industries.

Appendix 1 – 2011-12 Revenue and Expenditure

The APVMA received a total revenue of $34.96 million during the year ended 30 June 2012, $28.53 million of which was collected through registration fees, sales levies and other fees. In addition, the APVMA received appropriation funding of $135,000 for the minor use program, $653,000 as an interest offset payment and $119,000 in relation to the setting of Maximum Residue Limits.

In 2011 the government announced its intention to proceed with the Better Regulation of Agricultural Chemicals and Veterinary Medicines reforms. The reforms improve the efficiency and effectiveness of the regulation of agvet chemicals and introduce a number of new activities for the APVMA. During 2011-12, the APVMA received $5.33 million as a one-off Parliamentary appropriation to fund the Better Regulation of Agricultural Chemicals and Veterinary Medicines reforms[45].

The following table summarises the cost of the activities undertaken by the APVMA, along with the current or impending cost recovery arrangement. The costs stated are in accordance with the APVMA Activity Based Costing Model 2011-12, unless otherwise specified.

Activity	Cost Recovery Method	Cost for 2011-12
Pre-Market Regulation Activities		
Registration and approvals of products and active constituents[46]	Application fee and balance by levy	$ 14,405,796
Registrations to vary an existing product or label	Application fee and balance by levy	$ 4,188,882
Minor changes required by the APVMA	No fee is charged to the applicants. Activity is funded by the annual fee	$ 2,561,718
Permits for possession and export	Minor application fee and balance by levy	$ 82,738
Permit extensions	Minor application fee and balance by levy	$ 765,997
Minor use permits	Minor application fee and balance by levy	$ 411,023
Emergency use permits	No fee is charged to the applicants. Activity is funded by the levy	$ 152,132
Research and miscellaneous permits	Application fee and balance by levy	$ 877,945
Certificates of Export	Application fee	$ 79,407
Consents to Import	No fee is charged to the applicants. Activity is funded by the annual fee	$ 291,405
GMP[47] compliance	Specific categorised annual fees charged to manufacturers of veterinary medicines with an annual fee concession funded by industry	$ 1,455,026

[45] This appropriation formed part of the $8.75 million of government funding to implement reforms to the regulation of agvet chemicals in Australia. This funding was provided to the APVMA over four years, commencing from 2010.
[46] This includes fees paid to the Department of Health and the Department the Environment for scientific assessment services provided to the APVMA for specific product registrations, permit applications and assessments of chemicals.
[47] The Good Manufacturing Practice sets standards for domestic and international manufacturing facilities for veterinary medicines. The APVMA Cost Recovery Impact Statement 2013 – 2015 introduced an annual compliance assessment fee, a license application fee and a supplemental audit fee applicable to manufacturers of veterinary medicines from 1 July 2013.

Activity	Cost Recovery Method	Cost for 2011-12
Post-Market Regulation Activities		
HGP Scheme	Specific flat annual fee charged to HGP suppliers	$ 95,006
AgQA Scheme	Annual fee	$ 163,921
AERP and Chemical Review	Levy	$ 2,496,793
Compliance and enforcement	Annual fee	$ 2,068,942
Information Activities		
Website, annual report and corporate publications, consultative committees, presentation and seminars, information publishing scheme, informing policy and research	Levy with partial funding from government agencies for specific research projects	$ 1,336,21348

[48] This an estimation of the cost of corporate overheads, governance and reporting activities, which has been included as an overhead and allocated to the pre and post-market activities listed above.

Appendix 2 – Principles of the Cost Recovery Guidelines

The following are the key principles of cost recovery outlined in the Cost Recovery Guidelines:

1. Agencies should set charges to recover all the costs of products or services where it is efficient to do so, with partial cost recovery to apply only where new arrangements are phased in, where there are government endorsed community service obligations, or for explicit government policy purposes.
2. Cost recovery should not be applied where it is not cost effective, where it is inconsistent with government policy objectives or where it would unduly stifle competition or industry innovation.
3. Any charges should reflect the costs of providing the product or service and should generally be imposed on a fee-for-service basis or, where efficient, as a levy.
4. Agencies should ensure that all cost recovery arrangements have clear legal authority for the imposition of charges.
5. Costs that are not directly related or integral to the provision of products or services (e.g. some policy and parliamentary servicing functions) should not be recovered. Agencies that undertake regulatory activities should generally include administration costs when determining appropriate charges.
6. Where possible, cost recovery should be undertaken on an activity (or activity group) basis rather than across the agency as a whole. Cost recovery targets on an agency-wide basis are to be discontinued.
7. Products and services funded through the budget process form an agency's 'basic information product set' and should not be cost recovered. Commercial, additional and incremental products and services that are not funded through the budget process fall outside of an agency's 'basic product set' and may be appropriate to cost recover.
8. Portfolio Ministers should determine the most appropriate consultative mechanisms for their agencies' cost recovery arrangements, where relevant.
9. Cost recovery arrangements will be considered significant ('significant cost recovery arrangements') depending on both the amount of revenue and the impact on stakeholders. A 'significant cost recovery arrangement' is one where:
    a. an agency's total cost recovery receipts equal $5 million or more per annum - in this case every cost recovery arrangement within the agency is considered, prima facie, to be significant, regardless of individual activity totals; or
    b. an agency's cost recovery receipts are below $5 million per annum, but stakeholders are likely to be materially affected by the cost recovery initiative; or
    c. Ministers have determined the activity to be significant on a case-by-case basis.
10. Agencies with significant cost recovery arrangements should ensure that they undertake appropriate stakeholder consultation, including with relevant departments.
11. All agencies with significant cost recovery arrangements will need to prepare Cost Recovery Impact Statements (CRIS). A CRIS will not be required where a Regulation Impact Statement (RIS) that also addresses cost recovery arrangements against these guidelines has been prepared.
    a. The chief executive, secretary or board must certify that the CRIS complies with the policy and provide a copy to the Department of Finance and Administration.

   b. Agencies must include a summary of the CRIS in their portfolio budget submissions and statements.

12. Agencies are to review all significant cost recovery arrangements periodically, but no less frequently than every five years.
13. Agencies will need to separately identify all cost recovery revenues in notes to financial statements – to be published in portfolio budget statements and annual reports consistent with the Finance Minister's Orders.
14. Portfolio Ministers are responsible for ensuring that the cost recovery arrangements of agencies within their portfolios comply with the policy and will report on implementation and compliance in portfolio budget submissions.

Appendix 3 – Consultation during First Principles Review

Consultation with Australian and International regulatory agencies

Protiviti consulted the following Australian and international regulatory agencies across a range of industries to identify alternative cost recovery models. We consulted with representatives of these regulators to better understand the advantages, disadvantages and rationales behind the cost recovery arrangements in place within the agencies.

- National Offshore Petroleum Safety and Environment Management Authority (NOPSEMA);
- Food Standards Australia New Zealand (FSANZ);
- Australian Communications Media Authority (ACMA);
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS);
- Australian Sports Anti-Doping Authority (ASADA);
- Therapeutic Goods Administration (TGA);
- Australian Maritime Safety Authority (AMSA);
- Australian Fisheries Management Authority (AFMA);
- Australian Securities Investment Commission (ASIC);
- United Kingdom Chemicals Regulation Directorate (UK CRD);
- New Zealand Environment Protection Authority (NZ EPA);
- New Zealand Ministry of Primary Industries (NZ MPI);
- Germany – Federal Office of Consumer Protection and Food Safety; and
- Health Canada Pest Management Regulatory Agency (PMRA).

In addition, in order to obtain an understanding of the APVMA's cost recovery arrangements, Protiviti also consulted with the following agencies that provide Specialist Assessment Services to the APVMA:

- Department of Health - Office of Chemical Safety (OCS); and
- Department of Sustainability, Environment, Water, Population and Communities (DSEWPC) – Chemical Assessment Section, Environment Protection Branch.

Consultation on submissions received in relation to the First Principles Review, the Cost Recovery Discussion Paper and Cost Recovery of Compliance with GMP Supplementary Discussion Paper

Protiviti reviewed written submissions provided by industry members in relation to the initial call for submissions on First Principles Review (dated August 2012) and subsequent consultation paper (dated November 2013), the Cost Recovery Discussion Paper (dated December 2011) and the Cost Recovery of Compliance with GMP Supplementary Discussion Paper (dated May 2012):

- Accord Australia;
- Animal Health Alliance (AHA);
- Australian Custard Apple Growers Association (ACAGA);
- Australian Forest Products Association (AFPA);
- Australian Ginger Industry Association (AGIA);
- Australian Mango Industry Association Ltd. (AMIA);

- Australian Mushroom Growers Association (AMGA);
- AvantiAgri Australia;
- Biolab;
- Bell Laboratories Inc.;
- Chestnuts Australia Inc (CAI);
- Competitive Advantage;
- CropLife Australia;
- GrainGrowers;
- Grain Producers Australia (GPA);
- Growcom;
- GRC Institute;
- Hazelnut Growers of Australia Inc (HGA);
- Horticulture Australia Limited (HAL);
- National Farmers Federation (NFF);
- Nowra Chemical Manufacturers (NOWCHEM);
- NSW Farmers' Association (NSWFA);
- Nufarm Limited;
- Onions Australia;
- Organic Crop Protectants Pty Ltd;
- Plastics and Chemicals Industries Association (PACIA);
- Passionfruit Australia Inc.;
- Peanut Company of Australia;
- Pet Food Industry Association of Australia Inc (PFIAA);
- Pistachio Growers' Association Inc (PGAI);
- Pulse Australia;
- Raspberries & Blackberries Australia (RABA);
- Swimming Pool and Spa Alliance (SPASA);
- Sypharma Pty Ltd;
- Sumitomo Chemical;
- Veterinary Manufacturers and Distributors Association Ltd;
- Victorian Farmers Federation;
- Veterinary Manufacturers and Distributors Association Ltd (VDMA); and
- Western Australian Farmers Federation.

Protiviti provided an opportunity for all industry members who made a submission on the initial call for submissions on First Principles Review to meet to provide additional or to clarify issues from the written submission, and subsequently consulted with AFPA, CropLife and AHA.