



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



# COST RECOVERY DISCUSSION PAPER

Covering the period 1 July 2012-30 June 2015

Submissions close date: 28 February 2012

THIS PAGE INTENTIONALLY LEFT BLANK

---

## SUMMARY

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has prepared this Cost Recovery Discussion Paper to invite submissions from industry and other interested parties on the Authority's cost recovery arrangements for the period 1 July 2012 until 30 June 2015.

A fundamental review of the APVMA's cost recovery arrangements will be undertaken over the period 2012–14. This review will include all aspects of the APVMA's cost recovery arrangements and will be undertaken by the Department of Agriculture, Fisheries and Forestry in consultation with the APVMA and the Department of Finance and Deregulation.

The review will include consideration of whether or not to change the current policy to recover 60 per cent of assessment costs via a levy on sales. The review will include an examination of all existing fees and charges including alternate options and models to recover the APVMA's operating costs. As part of the review, separate consultation will occur with stakeholders and the state and territory governments.

The main purpose of this Cost Recovery Discussion Paper is to inform the development of interim cost recovery arrangements.

The paper focuses on compliance with the policy framework that was determined by the signatories to the National Registration Scheme and endorsed by the Primary Industries Standing Committee in 2002. It concentrates on ensuring appropriate and sustained revenue to enable efficient and effective administration of regulation and to minimise risks whilst the fundamental review of the APVMA's cost recovery arrangements is being undertaken.

The Cost Recovery Discussion Paper also provides information on expected efficiencies flowing from the Better Regulation of Agricultural and Veterinary Medicines, including those undertaken in 2010 and those to be implemented in 2012.

The reforms undertaken in 2010 resulted in significant timeframe and output improvements and the Better Regulation of Agricultural and Veterinary Chemicals reforms will allow the APVMA to further improve timeframe performance as outlined in this paper.

The paper discusses possible increases to the APVMA's compliance and enforcement capabilities. Finally, the Cost Recovery Discussion Paper provides information on the additional ongoing costs associated with the operation of a new Continuation of Approvals and Registration Scheme (resulting from the Better Regulation of Agricultural and Veterinary Chemicals reforms) and how these costs might be incorporated into the operating costs of the organisation.

A Cost Recovery Impact Statement (CRIS) will be developed in March 2012. The CRIS will consider submissions on this Cost Recovery Discussion Paper.

For enquiries, please contact:

Tony de la Fosse  
Program Manager Corporate Services  
Telephone: (02) 6210 4844  
Email address for submissions: [costrecovery@apvma.gov.au](mailto:costrecovery@apvma.gov.au)

Due date: 28 February 2012

Website: [http://www.apvma.gov.au/news\\_media/news/2011/2011-08-05\\_cost\\_recovery.php](http://www.apvma.gov.au/news_media/news/2011/2011-08-05_cost_recovery.php)

# CONTENTS

---

<b>SUMMARY</b>	<b>III</b>
<b>1 OVERVIEW</b>	<b>1</b>
<b>1.1 Purpose</b>	<b>1</b>
<b>1.2 Background</b>	<b>1</b>
<b>1.3 Australian Government Cost Recovery Policy</b>	<b>2</b>
The APVMA's approach to implementing the guidelines	3
<b>1.4 About the APVMA</b>	<b>4</b>
The APVMA's strategic framework	6
The existing cost recovery arrangements	7
Funding arrangements	8
Review of 40 per cent/60 per split between application fees and levy	9
The APVMA's operating expenditure	9
Financial performance	10
The financial reserve	11
<b>1.5 The agvet chemical industry</b>	<b>11</b>
<hr/>	
<b>2 POLICY REVIEW—ANALYSIS OF ACTIVITIES</b>	<b>16</b>
<b>2.1 The APVMA's activities</b>	<b>16</b>
<b>2.2 Registration and approvals</b>	<b>17</b>
Evaluation of applications for registration and approval	17
Evaluation of applications for Good Manufacturing Practice (GMP)	20
New Continuation Scheme (re-registration scheme)	20
Certificates of Export	21
Consents to Import	21
<b>2.3 Monitoring ongoing compliance with regulations</b>	<b>22</b>
Good Manufacturing Practice compliance audits	22
Hormonal Growth Promotant Scheme	22
Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products	22
Adverse Experience Reporting Program and Chemical Review	23
<b>2.4 Investigation and enforcement</b>	<b>24</b>
<b>2.5 Information activities</b>	<b>24</b>
<hr/>	
<b>3 DESIGN AND IMPLEMENTATION OF REVISED COST RECOVERY ARRANGEMENTS</b>	<b>25</b>
<b>3.1 The need to review cost recovery arrangements</b>	<b>25</b>
<b>3.2 Improving the existing arrangements</b>	<b>25</b>
<b>3.3 Legal requirements for the imposition of charges</b>	<b>26</b>
Which issues should any legislation address?	27
<b>3.4 The introduction of indexation</b>	<b>27</b>
<b>3.5 Registration and approvals</b>	<b>28</b>
Pre-application guidance (for product or active registration)	29
Fee Rebate	29
Evaluation of applications for Good Manufacturing Practice	33

Certificates of Export	36
Consent to Import	36
<b>3.6 Monitoring ongoing compliance with regulation</b>	<b>37</b>
Hormonal Growth Promotant Scheme	37
Quality Assurance Scheme for agricultural active constituents and agricultural chemical products (Ag QA Scheme)	37
Adverse Experience Reporting Program (AERP) and Chemical Review	38
<b>3.7 Investigation and enforcement</b>	<b>39</b>
<b>3.8 Information activities</b>	<b>39</b>
<b>3.9 The annual fee</b>	<b>39</b>
<b>3.10 The levy</b>	<b>41</b>
<b>3.11 Further improving timeframe performance</b>	<b>42</b>
Timeframe performance	42
Further timeframe performance improvements as a result of the Better Regulation of Pesticides and Veterinary Medicines reforms	44
<b>3.12 Increasing compliance and enforcement</b>	<b>45</b>
<b>3.13 Forecast operating results of proposed cost recovery arrangements</b>	<b>46</b>
<b>3.14 Impact on companies of different sizes</b>	<b>47</b>
<b>3.15 Implementation</b>	<b>47</b>
<b>3.16 Summary of charging arrangements 2012–13</b>	<b>49</b>
<b>3.17 Summary of fee and levy changes 2012-13 to 2015-16</b>	<b>55</b>
<hr/>	
<b>4 ONGOING MONITORING</b>	<b>66</b>
<b>4.1 Internal accountability structures</b>	<b>66</b>
<b>4.2 External accountability structures</b>	<b>66</b>
<b>4.3 Monitoring mechanisms</b>	<b>66</b>
<b>4.4 Periodic review</b>	<b>67</b>
<hr/>	
<b>5 STAKEHOLDER CONSULTATION</b>	<b>68</b>
<b>5.1 Consultation objectives</b>	<b>68</b>
<hr/>	
<b>APPENDIX A: COST RECOVERY MODEL</b>	<b>70</b>
Cost allocations	70
Method	70
Cost recovery model assumptions	73
Key changes to revenue streams	74
Operating result	75
Upfront cost recovery rate	76
Levy rates	76
<hr/>	
<b>APPENDIX B: SECTION CONTRIBUTION TO THE COST OF APPLICATIONS FOR REGISTRATION AND APPROVAL</b>	<b>78</b>
<b>APPENDIX C: IMPACT OF CHANGES OF COMPANIES OF DIFFERENT SIZES</b>	<b>81</b>
<b>GLOSSARY OF TERMS AND ABBREVIATIONS</b>	<b>84</b>

## LIST OF TABLES

Table 1: APVMA operating budget expenditure (not including reform funds) 2001–02 to 2010–11	10
Table 2: APVMA Financial Performance 2001–02 to 2010–11	10
Table 3: Agvet product distribution and sales by company size (2010–11)	12
Table 4: Agvet product distribution and product type (2010–11)	13
Table 5: Wholesale product sales (financial year 2010–11)	13
Table 6: Applications received	14
Table 7: Registered products at the beginning of the financial year 2003-04 to 2011–12	15
Table 8: Product lifecycle (only 2007–08 cohort of products)	15
Table 9: The APVMA's activities	16
Table 10: History of application fee revenue and registration and approval expenses	26
Table 11: Cost components of registration and approvals (2010–11 costs)*	33
Table 12: Cost components of GMP charges 2010–11	35
Table 13: Cost components of Certificates of Export charges 2010–11	36
Table 14: Cost components of Consent to Import activities 2010–11	36
Table 15: Cost components of the HGP Scheme charges 2010–11	37
Table 16: Cost components of the Ag QA Scheme charges 2010–11	38
Table 17: Cost components of the AERP and Chemical Review charges 2010–11	38
Table 18: Cost components of investigation and enforcement charges 2010–11	39
Table 19: 2014–15 annual fee revenue and activities funded by annual fees	41
Table 20: Levy rates	41
Table 21: Pesticide Program elapsed times and per cent finalised within timeframe 2009–10 and 2010–11	43
Table 22: Veterinary Medicines Program elapsed times and per cent finalised within timeframe 2009–10 and 2010–11	44
Table 23: Current timeframe performance targets 2011–12 to 2014–15	44
Table 24: Revised timeframe performance targets 2011–12 to 2014–15	45
Table 25: Forecast operating results 2011-12 to 2014–15	47
Table 26: Proposed implementation dates based on release of final CRIS before 30 June 2012	48
Table 27: Schedule of fees and charges 2012–13	49
Table 28: Table of fees and assessment periods	56
Table 29: Ongoing monitoring mechanisms for the revised cost recovery arrangements	67
Table 30: Detailed calculation of application fees payable on 1 July 2012 and 1 July 2013	71
Table 31: Summary of budget attribution (2011–12)	72
Table 32: Revenue composition	74
Table 33: Cost object revenue attribution 2012–13 to 2014–15	74
Table 34: Financial result	75
Table 35: Upfront cost recovery	76
Table 36: Levy rates	76
Table 37: Section contribution to the cost of application categories	78
Table 38: Section contribution to the cost of application categories (continued)	78
Table 39: Section contribution to the cost of application modules (continued)	79
Table 40: Section contribution to the cost of application modules (continued)	79
Table 41: Section contribution to the cost of application modules (continued)	80
Table 42: Section contribution to the cost of application modules (continued)	80
Table 43: Comparison of fees paid by a typical large company from 2011–12 to 2014–15	81
Table 44: Comparison of fees paid by a typical medium company from 2011–12 to 2014–15	82
Table 45: Comparison of fees paid by a typical small company from 2011–12 to 2014–15	83

## LIST OF FIGURES

Figure 1: APVMA organisational chart	5
Figure 2: Strategic framework	7
Figure 3: Process map for product registrations	19
Figure 4: Timeframe performance, 2009 to 2011	42
Figure 5: Design of cost recovery model	73



# 1 OVERVIEW

## 1.1 Purpose

The purpose of this Cost Recovery Discussion Paper is to seek stakeholder input/comments on possible changes for the cost recovery arrangements for the Australian Pesticides and Veterinary Medicines Authority (APVMA) to align them to the *Australian Government Cost Recovery Guidelines* (July 2005)<sup>1</sup> (the Guidelines) and establish:

- transparency and compliance with the Australian Government Cost Recovery Guidelines (Guidelines)
- a mechanism to recover the costs of operating a new Continuation Scheme introduced as part of the Better Regulation of Agricultural and Veterinary Chemicals (the Reform Agenda)
- the redirection of savings flowing from efficiencies from the Reform Agenda to offset reform costs, including additional evaluation resources to further improve timeframe performance
- stronger compliance and enforcement activities in line with the new compliance powers provided to the APVMA as part of the Reform Agenda
- the legal basis for charging, details of costing methods, links between the charge and the costs of providing the product or service, identification of the beneficiaries of the good or service, or the individuals or groups that have created the need for regulation
- an effective charging mechanism; that is, a fee for service or a levy
- appropriate stakeholder consultation.

## 1.2 Background

The current cost recovery arrangements of the APVMA were implemented in July 2005.

In early 2008, the APVMA commenced a review of its cost recovery arrangements. A draft Cost Recovery Impact Statement (CRIS) was released in December 2008. In early 2010, The Hon Tony Burke, Minister for Agriculture, Fisheries and Forestry, advised the APVMA that he had decided to increase a range of fees charged by the APVMA by 10 per cent, to be effective from 1 July 2010, rather than proceed with the implementation of the draft CRIS. This 10 per cent increase applied to the annual fee on product registrations, new application fees for evaluation and approval (category and modular), hormone growth promotant (HGP) notification number application and renewal fees, Certificate of Export fees, new good management practice (GMP) licences and database information fees. Levies did not change. At the time of the 10 per cent increase, it was announced that the increase was an interim measure and that further changes to the APVMA's cost recovery arrangements would be considered in the context of expected reforms to the operation of the APVMA.

The intention to introduce reforms was announced in the government's 2010 commitment for the Better Regulation of Agricultural and Veterinary Chemicals. A policy consultation paper was released in November 2010 which outlined a range of possible reforms that aim to improve the systems that protect human health, the environment and Australia's trade; reduce the regulatory burdens on industry and businesses; and enhance the APVMA's business and operational functions. These reforms build upon work undertaken in June 2010 that included a simplified process for applicants to make minor variations to chemical approvals or registrations (such as changing pack size); allowing companies to make minor

<sup>1</sup> *Australian Government Cost Recovery Guidelines* (July 2005) are available at <[http://www.finance.gov.au/publications/finance-circulars/2005/docs/Cost\\_Recovery\\_Guidelines.pdf](http://www.finance.gov.au/publications/finance-circulars/2005/docs/Cost_Recovery_Guidelines.pdf)>.

changes to chemical labels (such as changing a logo); and removing the requirement on registrants to notify the APVMA of an approved person.

In early 2011 the government announced its intention to proceed with the Better Regulation of Pesticides and Veterinary Medicines reforms. This Cost Recovery Discussion Paper builds upon the consultation undertaken as part of the draft 2008 CRIS. It is noteworthy that the 2008 draft CRIS was not approved and is not a government policy. A new Activity Based Costing exercise has been completed to incorporate efficiencies flowing from the 2010 legislative reforms.

The existing Primary Industries Standing Committee endorsed cost recovery policy framework has not been examined as part of this Cost Recovery Discussion Paper. Key issues discussed in this paper include the following:

- setting charges to recover costs as required in the government's Cost Recovery Guidelines
- recovering 40 per cent of the costs of evaluations (that lead to product registration) through upfront application fees; the remaining 60 per cent of evaluation costs will be recovered through the levy
- introducing indexation on fees (including the annual fee, application fees for registration and approval, Certificates of Export) to ensure they remain cost reflective over time in accordance with their original policy intent)
- examining ways to establish more equitable cost recovery for the Manufacturing Licensing Scheme (MLS) for veterinary medicines as foreshadowed in the 2005 CRIS and draft 2009 CRIS, whereby products that involve MLS pay an equal share towards both the cost of the MLS and a share of the cost of compliance and enforcement, chemical review, and the Adverse Experience Reporting Program through an annual fee
- establishing new arrangements such that non-MLS vet products and all agricultural products pay an equal share towards both the cost of compliance and enforcement, chemical review, and the Adverse Experience Reporting Program through an annual fee
- increasing the budget base to allow for the ongoing recovery of costs associated with the operation of a new Continuation Scheme
- including a possible adjustment to increase compliance and enforcement capabilities
- examining how the APVMA can make further improvements in timeframe performance
- examining if the APVMA should introduce a rebate if the APVMA fails to finalise an application within the specified statutory timeframe
- recovering 100 per cent of the cost for Category 17 (imagined active constituent applications).

### **1.3 Australian Government Cost Recovery Policy**

In December 2002, the Australian Government adopted a formal cost recovery policy to improve the consistency, transparency and accountability of its cost recovery arrangements and promote the efficient allocation of resources. The cost recovery policy is administered by the Department of Finance and Deregulation; it is also outlined in the Guidelines, and the review schedule is outlined in *Finance Circular* 2005/09 and 2008/08. The underlying principle of the policy is that agencies should set charges to recover all the costs of products or services where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group, and where charging is consistent with Australian Government policy objectives.

The policy applies to all *Financial Management and Accountability Act 1997* (FMA Act) agencies and to relevant *Commonwealth Authorities and Companies Act 1997* (CAC Act) bodies that have been notified, under sections 48A of the CAC Act and compliance with General Policy Orders under sections 28 or 43 in applying the cost recovery policy. The APVMA is an FMA Act agency. In line with the policy, individual portfolio ministers are ultimately responsible for ensuring agencies' implementation and compliance with the cost recovery guidelines.

## The APVMA's approach to implementing the guidelines

The Better Regulation of Agricultural and Veterinary Chemical Products review was considered by Cabinet in April 2011. A CRIS will be developed in early 2012 which will enable the reforms agreed by Cabinet to be implemented. This includes setting out a cost-recovery framework for a new system of continuation of approvals and registrations (a re-registration scheme), the introduction of a graduated compliance and enforcement regime and changes to the cost-recovery arrangements for approvals, registrations, permits and regulatory guidance.

The APVMA has prepared this consultation paper in accordance with the Guidelines including the following key principles:

- charges should be set to recover the costs of products and 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
- 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
- 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
- that there is clear legal authority for the imposition of charges
- costs that are not directly related or integral to the provision of products or services (for example some policy and parliamentary servicing functions) should not be recovered; administrative costs should generally be included when determining appropriate charges
- cost recovery is undertaken on an activity basis; direct and indirect costs are attributed to each key activity according to an industry standard activity based costing (ABC) model
- products and services funded through the budget process form the APVMA's 'basic product set' should not be cost recovered. The APVMA receives around \$133 000 a year of appropriated funds towards its activities on Minor Use and about \$630 000 a year to compensate for lost interest earnings following the move to the FMA Act.

The APVMA is using the cost recovery framework determined by the Signatories Working Group (SWG) and endorsed by the Primary Industries Standing Committee (PISC) as the baseline position for this review. Changes to the legislation and the overarching policy arrangements of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), including its cost recovery framework, should be made with the consent of all signatories to the agreement. This Cost Recovery Discussion Paper is informed by previous consultation undertaken in 2008–09 as part of a draft CRIS.

In August 2011, PricewaterhouseCoopers undertook an ABC exercise to collect current data to establish the current cost of activities.

Several factors—such as the current cost recovery framework, costs associated with the ongoing operation of the Continuation Scheme, and results of the ABC study—form the basis of the APVMA's

financial modelling to determine appropriate fees and levies that are consistent with the Guidelines (refer to **Appendix A**).

Section 5 discusses the APVMA's mechanisms for ongoing monitoring of the proposed revised cost recovery arrangements in more detail.

## 1.4 About the APVMA

The APVMA is the independent Australian Government statutory authority responsible for the assessment and registration of pesticides and veterinary medicines (agvet chemicals) and for their regulation up to and including the point of retail sale.

The APVMA is responsible for administering and managing the NRS, which sets out the regulatory arrangements for the management of agvet chemicals in Australia. The APVMA administers the NRS's legislation in partnership with state and territory governments and with the active involvement of other Australian Government agencies.

The role of the APVMA is to independently evaluate the safety and performance of agvet chemicals intended for supply within Australia, ensuring that the health and safety of people, animals, crops, the environment and trade are protected. All registered products must be shown to work and be safe for people and the environment. Registered products must also not unduly jeopardise Australia's trade with other nations.

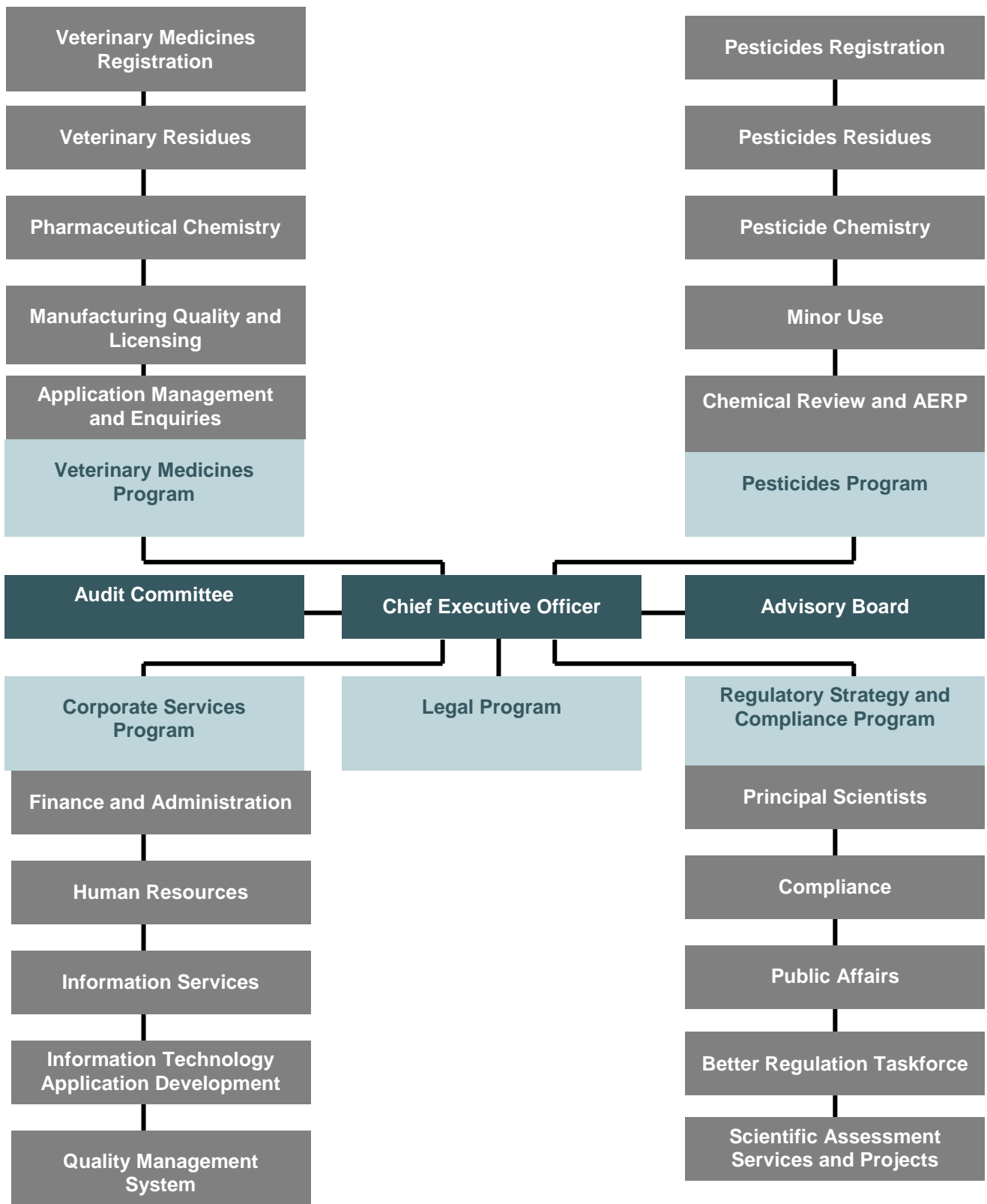
To ensure that only those products that meet the APVMA's requirements are actually supplied, the APVMA constantly monitors the market for product compliance. The APVMA also reviews registered chemical products to ensure that they continue to meet contemporary standards of quality, safety and efficacy.

The states and territories are responsible for regulating and managing the use of agvet chemicals once they are sold.

The chemical industry and users of agvet chemicals benefit from the NRS by the provision of uniformity in the assessment, approval and registration processes and by improved access to agvet chemicals and markets for products nationally and internationally. Both of these factors have the effect of reducing the regulatory burden and associated market entry and compliance costs associated with agvet chemicals.

The APVMA's current organisational chart is shown in Figure 1.

Figure 1: APVMA organisational chart



## The APVMA's strategic framework

Given the need to use agvet chemicals for pest and disease control, the work of the APVMA protects the health and safety of people, animals, the environment and Australia's trade. The APVMA's activities also support the Australian agriculture and livestock industries.

The APVMA has developed a performance framework that links its legislative objectives to an outcome–outputs model. The APVMA's performance framework is shown in Figure 2 and involves a detailed planning and reporting process incorporating the portfolio budget statement, corporate plan, operational plan and annual report.

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 since 1996. As a consequence of the complex intergovernmental governance arrangements for the NRS, any changes to the legislation and the overarching policy arrangements of the NRS, including its cost recovery arrangements, should be made with the consent of all signatories to the agreement.

In the late 1990s, the Australian, state and territory governments commissioned a National Competition Policy legislation review of agvet chemicals legislation (National Competition Policy Review 1999—NCPR) for the then National Registration Authority.<sup>2</sup> The NCPR was a result of an agreement by all Australian governments to adopt a consistent approach to improving the competitiveness of the Australian economy. The NCPR final report, published in 1999, made several recommendations in relation to the APVMA's cost recovery arrangements, which aimed to remove discrimination between firms regarding their payments to the APVMA and potential hurdles to smaller businesses seeking registration of agvet chemical products.

The NCPR recommended that:

- the levy be changed to a simple flat rate levy (applied at the point of wholesale sale) with no exemptions or caps
- the annual renewal fees should be abolished and a minimum levy liability (per registered product) set instead
- application and other registration service fees should reflect the costs.

The intergovernmental response to the NCPR supported the intent of those recommendations. However, it was noted that the NCPR was silent on the question of the balance between revenue sources. To address this, the Australian Government established a committee composed of representatives of Australian, state and territory governments—the SWG—to examine this issue. The SWG determined that the most appropriate and effective cost recovery model should be based on:

- a modular fee structure and the establishment of a recovery rate of 40 per cent of the cost of the evaluations that lead to product registration
- 100 per cent cost recovery for administrative services, including export certificates
- the levy rate being set as the balancing factor (that is, the difference between the APVMA's annual income from these sources, and its annual expenditure).

---

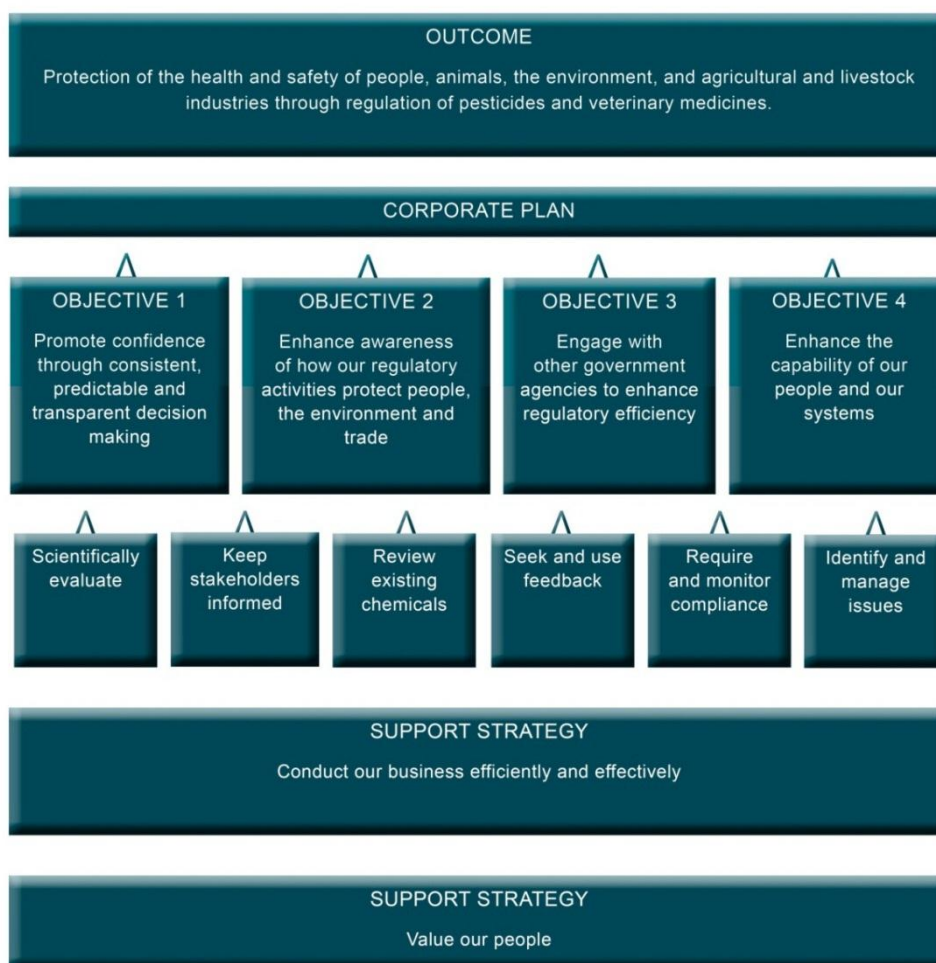
<sup>2</sup> The APVMA was formerly known as the National Registration Authority (1996–2003).

The SWG recommended that the cost of assessing applications for registration and approval be paid as an application fee (nominal fee of 40 per cent), with the remainder recovered across the life of the product through the levy collected from companies at the point of wholesale sale and presumably transferred to the users of agvet chemicals through the pricing mechanism.

The SWG considered that a higher level of cost recovery through the application fee would be a significant disincentive for new products and innovation into the market, particularly in the case of small businesses, niche products, and chemical products that have a low value of sales.

In line with the legislative arrangements for establishment of policy relating to the NRS, these principles were endorsed by the PISC in July 2002.

Figure 2: Strategic framework



### The existing cost recovery arrangements

The APVMA's current cost recovery arrangements were implemented in July 2005. They incorporated the SWG's recommendations, with the exception of the implementation of a minimum levy. The 2005 CRIS established:

- application fees based on 40 per cent recovery of the cost of technical evaluations leading to registration, and 100 per cent cost recovery for administrative services

- a \$390 annual fee on product registrations to cover costs of Category 13 applications;<sup>3</sup> costs associated with investigation, enforcement and support; and the costs of maintaining the product on the register
- a tiered levy based on wholesale-sales values of registered products for the previous year to cover the remaining 60 per cent of the cost of technical evaluations
- no cap on the levy or minimum sales levy
- a flat \$320 permit fee except for emergency use permits and some permits where a government agency is the permit holder
- a \$6 000 licence fee for the Manufacturers' Licensing Scheme (MLS) paid in instalments between four and 40 years<sup>4</sup>.

As previously noted, in early 2010 The Hon. Tony Burke, Minister for Agriculture, Fisheries and Forestry, advised that he had decided to increase a range of fees charged by the APVMA by 10 per cent, to be effective from 1 July 2010, rather than proceed with the implementation of a new CRIS. The decision to defer the 2009 CRIS was made in the context of the emerging Reform Agenda.

The 10 per cent increase applied to the annual fee on product registrations, new application fees for evaluation and approval (category and modular including permit applications]), Hormonal Growth Promotant (HGP) notification number application and renewal fees, Certificate of Export fees, new Good Manufacturing Practice (GMP) licences and database information fees. Levies did not change.

## Funding arrangements

The APVMA's activities are funded through cost recovery, except for a minor budgetary appropriation and a small amount of income from other sources. Since 1996, the APVMA has received an appropriation of about \$133 000 each year towards Minor Use activities. From 1 July 2007 the APVMA has also received about \$650 000 a year to compensate for lost interest earning following the move to the FMA Act from 1 July 2007.

Most of the APVMA's operational income is collected from registrants of agvet chemicals. Registrants pay application fees to register products and an annual fee to maintain products on the register for the next financial year. Registrants also pay annual levies based on the value of past sales of registered products. Administrative services attract a direct fee.

In 2010–11, payments of application fees, levies and annual fees by the agvet chemical industry represented 96 per cent of the APVMA's total revenue (excluding 'one-off' reform funds). It was 94 per cent in 2009–10 and 96 per cent in 2008–09.

In its 2010–11 mid-year economic and fiscal outlook statement, the government announced \$8.75 million of funding over four years to implement reforms to the regulation of agvet chemicals in Australia as part of the Reform Agenda. This funding is not 'ongoing', rather it relates only to the initial establishment and implementation of the reforms. The funding is for the implementation of seven key reform areas, as agreed by Cabinet in April 2011. These key reform areas are:

3 Category 13 is an application category for which there is no fee. Category 13 applications are to vary particulars or conditions of registration or listed registration and/or label approval if the variation is to allow a minor change, no data of a technical nature are required, and the variation is a change required by the APVMA. Category 13 applications replaced Category 38 applications in the revised application structure introduced on 1 July 2005.

4 There was no change to the MLS as a result of the 2005 CRIS. The scheme was however recommended for review.

1. Publication of a comprehensive risk framework that describes how the APVMA carries out its functions.
2. Enhancements to the efficiency and effectiveness of registration of products, approval of active constituents, review of chemicals and issuing of permits. This reform also includes enhancements to the APVMA's data protection provisions.
3. Extending the use of overseas data and assessments where these are relevant to the Australian setting.
4. Introduction of a continuation scheme for approvals of active constituents and registrations of chemical products (a re-registration scheme). The scheme will consider the entire chemical inventory against contemporary safety standards.
5. Improvements to the efficiency and transparency of the APVMA Advisory Board.
6. Establishing an independent panel to report on progress against the chemical review backlog and improvements in application and assessment processes.
7. Introduction of a modern and graduated compliance and enforcement regime.

The funding also covers the implementation of a Electronic Document and Records Management System (EDRMS) and the improvement of APVMA IT systems. Finally, the funding will be used to establish a taskforce to lead the implementation of the reforms and fund offsets to allow non-taskforce staff to participate in reform activities while maintaining core business activities.

Ongoing costs associated with the Reform Agenda are discussed in this Cost Recovery Discussion Paper. Two million dollars of the Reform Agenda funding is to be repaid to government in 2012–13 and 2013–14.

### Review of 40 per cent/60 per split between application fees and levy

The Primary Industries Standing Committee accepted advice from the signatories to the Inter-Governmental Agreement which established the APVMA that the costs of processing applications should be based on a 40 per cent upfront fee with the remainder recouped through a levy on product sales. The intention of this policy decision was to foster innovation and not disadvantage smaller companies in the market through the imposition of high upfront fees. This Cost Recovery Discussion Paper has been prepared on the basis of this existing policy position.

The Department of Agriculture, Fisheries and Forestry has indicated that during 2012 work will commence to complete detailed economic analysis to review the existing 40 per cent / 60 per cent policy as part of the current COAG reform agenda. This economic analysis will inform the fundamental review of the APVMA's cost recovery arrangements to be undertaken over the period 2012 - 2014. A new CRIS will be developed to incorporate changes prior to 30 June 2015.

### The APVMA's operating expenditure

The APVMA has shown strong budget control to maintain expenditure at levels below the average Consumer Price Index for the period particularly at a time when the APVMA has been asked to implement a range of new initiatives and activities without dedicated funding. For example, the APVMA has implemented a range of additional activities including the following:

- the establishment of an Adverse Experience Reporting Program in 2004
- the establishment of the data protection system in 2004–05
- the introduction of new labelling requirements in 2009–10

- responding to enhanced Freedom of Information legislation and significantly increased requests for information.
- the implementation of the Information Publication Scheme in 2010–11.

The APVMA's operating budget expenditure from 2001–02 to 2010–11 is shown in Table 1. Expenditure has increased by 25.37 per cent or an average of **2.54 per cent** per year during this period. During the same period, the Consumer Price Index has increased by 2.92 per cent on average.

**TABLE 1: APVMA OPERATING BUDGET EXPENDITURE (NOT INCLUDING REFORM FUNDS) 2001-02 TO 2010-11**

FINANCIAL YEAR	EXPENDITURE \$mil	INCREASE / DECREASE FROM PREVIOUS YEAR	NOTES
2001–02	20.624		
2002–03	20.202	-2.05%	
2003–04	21.636	7.10%	Establishment of Data Protection system and AERP and take up of WIP for SAS
2004–05	20.574	-4.91%	
2005–06	21.264	3.35%	
2006–07	23.242	9.30%	Move to new accommodation
2007–08	24.850	6.92%	
2008–09	25.864	4.08%	
2009–10	26.063	0.77%	
2010–11	25.856	-0.79%	

## Financial performance

Table 2 shows the APVMA's financial performance from 2001 to 2011. Periods of lower-than-average rainfall or drought have resulted in lower agvet chemical use, and this directly causes lower levy revenue in the following year. For example, the impact of the 2002–03 drought, which affected significant areas of rural Australia, resulted in significantly reduced levy revenue in 2003–04 and 2004–05. Likewise, the impact of the 2006–08 drought can also be seen in sharply lower income in 2007–08 and beyond.

**TABLE 2: APVMA FINANCIAL PERFORMANCE 2001-02 TO 2010-11**

FINANCIAL YEAR	INCOME (\$mil)	EXPENDITURE (\$mil)	SURPLUS/ (DEFICIT) (\$mil)	CLOSING EQUITY (\$mil)
2001–02	19.764	20.624	(0.860)	8.648
2002–03	19.514	20.202	(0.688)*	7.894
2003–04	18.103	21.636	(3.533)*	4.361
2004–05	19.307	20.574	(1.267)	3.067
2005–06	24.363	21.264	3.099	6.212
2006–07	25.330	23.242	2.088	8.296

FINANCIAL YEAR	INCOME (\$mil)	EXPENDITURE (\$mil)	SURPLUS/ (DEFICIT) (\$mil)	CLOSING EQUITY (\$mil)
2007–08	22.463	24.850	(2.387)*	5.909
2008–09	24.827	25.864	(1.037)*	4.871
2009–10	24.779	26.063	(1.284)*	3.727
2010–11	27.537	25.856	1.681	5.408

\*Drought years

Levy income made up 66 per cent of the APVMA's total income in 2010–11. To the extent it is consistent with Australian Government cost recovery guidelines, the APVMA believes it would be prudent to reduce the reliance on the levy and thus lower the potential impact of income fluctuations flowing from drought events.

This Cost Recovery Discussion Paper notes that the changes discussed could lower the APVMA's reliance on the levy from 66 per cent to 40 per cent of the APVMA's total income.

## The financial reserve

As the APVMA's revenue can vary significantly from year to year, as a result of fluctuations in agvet chemical sales, the APVMA holds a financial reserve. This reserve forms part of the APVMA's equity and allows revenue fluctuations to be managed. Without this financial reserve, the APVMA would risk periods where its liabilities exceed its assets (negative equity). The financial reserve is currently set at three months of operating expenses (\$6 million in 2011–12). Without this 'buffer', the APVMA could lapse into negative equity, which would breach financial regulations.

At 30 June 2011, the APVMA's equity (excluding unspent one-off Reform Agenda funding) was \$5.4 million, which is approximately \$0.6 million below its target reserve.

As net expenditure increases, the APVMA would normally increase the financial reserve to ensure it represents approximately three months of operating expenses. This would require it to be increased from its current level of \$6 million to \$7 million in 2012–13. However, if implemented, the changes outlined in this Cost Recovery Discussion Paper could lower the APVMA's overall reliance on the levy (moving it from 66 per cent of total income to around 40 per cent of total income) allowing the APVMA to reduce the reserve to two months of operating expenses for the period 2012-2015. This will allow the reserve to be maintained at around \$6 million and not increased over the period 2012-2015.

## 1.5 The agvet chemical industry

The agvet chemical 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 size of companies ranges from single-person businesses to large multinational companies.

## Agvet product sales

The APVMA does not collect detailed financial information on company sizes (such as total revenue or total equity). For the purpose of this analysis, the APVMA defines a small company as one that has wholesale agvet chemical product sales of less than \$5 million a year, a medium company as one with wholesale agvet chemical product sales of between \$5 million and \$20 million a year, and a large company as one with wholesale agvet chemical product sales of greater than \$20 million a year. The APVMA accepts that this definition does not take into account companies that derive revenue from other sources.

In 2010–11, the levy on wholesale product sales represented approximately 66 per cent of the APVMA's total revenue. As illustrated in Table 3, for the financial year 2010–11,<sup>5</sup> a total of 843 companies renewed registrations on a total of 9 551 agvet chemical products, and the majority of these companies (770) had sales of less than \$5 million.

Other highlights from the 2010–11 company-level analysis are:

- of the 843 companies with registered agvet products, 176 companies had all products with zero product sales
- another 594 companies had sales of less than \$5 million
- the 594 small companies had a total of 3 814 products registered
- the average product sales for small companies was \$93 000
- the average product sales for medium companies was \$199 000
- the average product sales for large companies was \$686 000.

**TABLE 3: AGVET PRODUCT DISTRIBUTION AND SALES BY COMPANY SIZE (2010-11)**

	ZERO ANNUAL SALES	SMALL COMPANY (ANNUAL SALES > \$1 - < \$5m)	MEDIUM COMPANY (ANNUAL SALES > \$5m - < \$20m)	LARGE COMPANY (ANNUAL SALES > \$20m)	TOTAL
Total companies (no.)	176	594	43	30	<b>843</b>
Total annual sales (\$ million)	-	353.404	413.005	2 197.352	<b>2 963.761</b>
Average annual sales per company (\$ million)	-	0.595	9.605	73.245	<b>3.516</b>
Total products (no.)	456	3 814	2 078	3 203	<b>9 551</b>
Average annual sales per product (\$ million)	0.000	0.093	0.199	0.686	<b>0.310</b>

Table 4 shows that agricultural companies are 72 per cent of companies with registered products, and their products represent 65 per cent of the total number of products registered by the APVMA. The average annual sales per company are comparable whilst the annual average sales per product are higher in agricultural companies than veterinary companies.

<sup>5</sup> Note: the APVMA's 2010-11 levy income is based on 2009-10 wholesale product sales.

TABLE 4: AGVET PRODUCT DISTRIBUTION AND PRODUCT TYPE (2010-11)

	AGRICULTURAL PRODUCTS	VETERINARY PRODUCTS	TOTAL
Companies (no.)	603	240	843
Percentage of companies (%)	72	28	100
Total annual sales in 2009-10 (\$ million)	2 143.324	820.437	2 963.761
Average annual sales per company (\$ million)	3.554	3.418	3.516
Total products (no.)	6 245	3 306	9 551
Percentage of products (%)	65	35	100
Average annual sales per product (\$ million)	0.343	0.248	0.310

Sales of most products are relatively low because Australia is a small market in global terms. Table 5 illustrates that about half the products in the market earn less than \$25 000 in sales, and more than a third of the registered products have no sales. As illustrated in Table 8 the majority of these products continue to record nil sales in subsequent years; that is, the APVMA does not recover 60 per cent of the cost of the application.

TABLE 5: WHOLESALE PRODUCT SALES (FINANCIAL YEAR 2010-11)

PRODUCT SALES THRESHOLDS (\$)	AG PRODUCTS (no.)	AG SALES (\$)	VET PRODUCTS (no.)	VET SALES (\$)	TOTAL PRODUCTS (no.)	TOTAL SALES (\$)
0	2 283	0	937	0	3 220	0
1–10 000	624	2 536 407	391	1 675 282	1 015	4 211 689
10 001–25 000	406	6 877 126	310	5 189 751	716	12 066 877
25 001–100 000	951	53 495 657	605	32 573 049	1 556	86 068 706
100 001–250 000	695	113 382 230	410	66 372 245	1 105	179 754 475
250 001–1 000 000	841	420 869 154	471	235 342 847	1 312	656 212 001
1 000 001–5 000 000	374	756 916 109	169	332 758 103	543	1 089 674 212
Greater than 5 000 000	71	789 247 739	13	146 525 813	84	935 773 552
<b>Total</b>	<b>6 245</b>	<b>2 143 324 422</b>	<b>3 306</b>	<b>820 437 090</b>	<b>9 551</b>	<b>2 963 761 512</b>

The structure of the Australian agvet chemical market based on the wholesale agvet chemical sales data has significant implications in terms of the design of any reform to the cost recovery arrangements. Cost recovery arrangements that place a higher relative financial burden upon smaller manufacturers and low-sales chemicals have the potential to reduce the range of chemical tools available. In particular, and to be consistent with the SWG guidance, the APVMA wishes to promote innovation. Care must be taken to ensure that the cost recovery arrangements are designed accordingly. This aspect is an important consideration in this review.

### *Agvet product sales variability*

The wholesale value of veterinary product sales tends to be relatively stable, whereas the wholesale value of agricultural product sales is more tightly linked to climatic conditions. The baseline (2009–10) ratio of agricultural to veterinary products sales is 2.61:1. The APVMA has identified that, in previous years, the ratio had been as high as 3.65:1. The effect of such a ratio change on the levy revenue could be as much as \$5 million, highlighting the importance of reducing the reliance on the levy as a source of revenue.

### *Agvet applications*

The APVMA recovers some product evaluation costs through upfront charging of application fees. The 2005 CRIS established a new application category and fee structure. Due to this change, it is not possible to make direct comparisons with application volumes at the category and module level over time. Table 6 below sets out the total number of product applications processed by the APVMA since 2003–04. The total number of applications received has increased substantially in 2010–11. Twenty-three per cent more applications for product registration, variation to registration or label approval for agricultural chemical products were received in 2010–11 than in 2009–10.

**TABLE 6: APPLICATIONS RECEIVED**

YEAR	AG APPLICATIONS RECEIVED	VET APPLICATIONS RECEIVED	TOTAL APPLICATIONS RECEIVED
2003–04	1 763	1 038	2 801
2004–05	1 398	979	2 377
2005–06	1 398	804	2 202
2006–07	1 551	888	2 439
2007–08	1 543	838	2 381
2008–09	1 583	911	2 494
2009–10	1 656	911	2 567
2010–11	2 044	1 112	3 156

### *Registered products*

Under the current arrangements, the annual fee on all registered products is set to recover the cost of product registrations to cover costs of Category 13 applications; costs associated with investigation, enforcement and support; and the costs of maintaining the product on the register. Table 7 highlights the total number of registered products attracting an annual fee each year since 2003–04. The total number of registered products has increased by around 4 per cent a year during the past five years. The change in annual fees in the 2005 CRIS from between \$200 and \$1 000 to a fixed annual fee of \$390 in 2005–06, and a further increase to \$430 in 2009–10, appear to have had no effect on the number of products on the register.

TABLE 7: REGISTERED PRODUCTS AT THE BEGINNING OF THE FINANCIAL YEAR 2003-04 TO 2011-12

YEAR	REGISTERED PRODUCTS (NO)	ANNUAL FEE (\$)
2003-04	7 717	200-1 000
2004-05	8 027	200-1 000
2005-06	8 031	390
2006-07	8 167	390
2007-08	8 342	390
2008-09	8 624	390
2009-10	8 837	390
2010-11	9 085	430
2011-12	9 720	430

### Product lifecycle

Table 8 below outlines the lifecycle of the 2007-08 stock of registered products. It does not include products added in the years following 2007-08. Analysis of the lifecycle of these registered products shows that many of the same products continually achieved nil sales over the three years examined.

Some of these products could only have been just registered and not yet marketed, or the registrations could be a 'shelf registration' where, intentionally, the product is never sold. It is also possible that the registrant has commercial arrangements with other entities to sell the product under a different brand name as a 'repack' of the original registration.

The table highlights that, of the 9 011 registered products in 2007-08, 397 were 'stopped' (not renewed at year's end) in 2008-09. A total of 791 were stopped across both years. The reason the overall number of registered products has increased is that, every year, the number of new product registrations is greater than the number of stopped registrations.

TABLE 8: PRODUCT LIFECYCLE (ONLY 2007-08 COHORT OF PRODUCTS)

PRODUCT SALES THRESHOLD	PRODUCT 2007-08 (no.)	SALES IN 2008-09				SALES IN 2009-10			
		0 (no.)	1-10 000 (no.)	< 10 000 (no.)	NOT RENEWED (no.)	0 (no.)	1-10 000 (no.)	< 10 000 (no.)	NOT RENEWED (no.)
0	2839	2218	108	216	297	1894	107	309	529
1-10 000	1081	161	679	186	55	241	530	211	99
< 10 000	5091	261	217	4568	45	423	249	4256	163
<b>Total</b>	<b>9011</b>	<b>2640</b>	<b>1004</b>	<b>4970</b>	<b>397</b>	<b>2558</b>	<b>886</b>	<b>4776</b>	<b>791</b>

## 2 POLICY REVIEW—ANALYSIS OF ACTIVITIES

### 2.1 The APVMA’s activities

This section aims to assess the appropriateness of cost recovery arrangements for each of the APVMA’s activities by defining:

- the purpose of the activity and who benefits from or creates the need for the activity
- whether cost recovery would undermine the objectives of the activity.

The Guidelines categorise activities undertaken by Australian Government agencies into regulatory activities and information activities. The Guidelines further classify regulatory activities into pre-market and post-market regulation activities. This classification and the relevance to the APVMA are described in Table 9.

TABLE 9: THE APVMA’S ACTIVITIES

ACTIVITIES		RELEVANCE TO APVMA
Pre-market regulation activities	A. REGISTRATION AND APPROVALS (SECTION 2.2)	<ul style="list-style-type: none"> <li>• Registration and Approvals—evaluation of applications (including permits)</li> <li>• Good Manufacturing Practice (GMP) compliance—evaluation of applications compliance -</li> <li>• Certificates of Export</li> <li>• Consents to Import</li> </ul>
	B. ISSUING EXCLUSIVE RIGHTS AND PRIVILEGES	Not performed by the APVMA—see discussion on data protection in following section
Post-market regulation activities	C. MONITORING ONGOING COMPLIANCE WITH REGULATIONS (SECTION 2.3)	<ul style="list-style-type: none"> <li>• GMP compliance audits</li> <li>• Hormone Growth Promotant Scheme</li> <li>• Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (Ag QA Scheme)</li> <li>• Adverse Experience Reporting Program (AERP)</li> <li>• Chemical Review</li> <li>• Continuation</li> </ul>
	D. INVESTIGATION AND ENFORCEMENT (SECTION 2.4)	<ul style="list-style-type: none"> <li>• Compliance and enforcement</li> </ul>
Information activities	E. INFORMATION ACTIVITIES (SECTION 2.5)	<ul style="list-style-type: none"> <li>• Website</li> <li>• Corporate publications</li> <li>• Presentations and seminars</li> <li>• Consultative committees</li> <li>• Informing policy</li> </ul>

Each of the APVMA’s activities are analysed in the following pages according to the structured questions outlined in the Guidelines.

## 2.2 Registration and approvals

### Evaluation of applications for registration and approval

Anyone who wishes to supply agvet chemicals must apply to the APVMA to register the products and obtain approval for labels attached to product containers before the products can be supplied, sold, distributed and used in Australia.

Companies or individuals who hold a registration for a pesticide or veterinary medicine must also seek approval for any variation to the particulars or conditions of registration, product, additional claims made about it, or changes to its label. Some variations are permitted under APVMA permit provisions, without APVMA approval.

Registration is based on a rigorous and independent evaluation of scientific information related to the safety and efficacy of a product. The APVMA grants registration if the evaluation of a product has shown that it is not likely to be harmful to target crops or animals, or to users, consumers and the environment. The evaluation also has to demonstrate that the product is effective and suitably formulated, and that its label contains adequate instructions. The APVMA must also assess whether using the product may unduly prejudice trade.

The primary processing functions for agvet chemical products are consistent. Figure 3 outlines the process for registering agvet chemical products.

### Data protection provisions of the Agvet Code

In order to have an active constituent approved or a chemical product registered, the applicant must submit a package of information for assessment by the APVMA. Under data protection provisions that began on 1 January 2005, opportunities to 'free ride' (by a second applicant on the approval or registration of a previous applicant) were reduced. Under the provisions, data protection applies to certain information, which is required and relied upon by the APVMA in making the decision for registration and approval. The only information that is protected in this way is information that has been submitted in support of applications for an approval of an active constituent, registration of a chemical product, approval of the relevant label particulars of a product container label, or variation to a registration or label approval.

Applicants do not apply for data protection as a separate process from approval or registration, and there is no separate legal process conferring rights or privileges. Unlike the issue of a patent, the first applicant will receive no compensation if the second applicant gains approval or registration using their own information for the same or similar products.

Under data protection provisions, the information held by the APVMA in relation to a first application cannot be used by the APVMA in the consideration of another application unless the second applicant has the consent of the authorising party. The payment of compensation for the use of this information is a private transaction, with the price to be set by negotiation between the parties.

If a second applicant generates their own information in support of their application, this will be treated as if it is a novel application. It will be assessed and charged accordingly, with no reference to the information, assessment, or determinations associated with the first application.

If a second applicant pays compensation to the first applicant and receives authorisation for the APVMA to access protected data in support of the second application, there is an argument to use a lower cost

category for the new application. That is, the second application can reference the registered product thereby allowing the application to be lodged in a lower cost category.

#### Expiry of data protection

Data protection periods have been set to provide an innovator with sufficient time in which to recoup the costs of generating the information through sales of products. If data protection applies, the extent of free riding is significantly decreased and occurs only after a period of protection has been provided, as once the period of data protection ends for a product, the APVMA will be able to use that information in its assessment of other applications without requiring consent from the authorising party.

In many cases, most of the cost of information has been recovered in other overseas markets and the main cost to be recouped is for information that is specific to Australian circumstances—Australia requires only a minor amount of additional data beyond that which is produced for the major overseas markets. Consequently, the full marginal costs of entering the Australian market are significantly less than those for the major overseas markets.

Nevertheless, given the small size of the Australian market, some products will have limited sales and some innovators may not be able to capture even these costs within the data protection period. Consequently, it is possible for some free riding to occur once the period to recover the innovation costs has expired.

#### Products registered before the introduction of data protection

Some free riding might continue because the data protection provisions are not retrospective and do not apply to information provided in support of applications submitted before 1 January 2005. This is unavoidable. It is a consequence of the history of the relevant legislation, which established the market entry conditions that were accepted by the applicants at the time of their application.

While assessment of subsequent applications will continue to be based on information submitted for the first application, it is likely that additional information and assessment would still be needed for most subsequent applications, either to support different formulations or uses or to demonstrate that the product is the same or similar. Although the original information will not be protected, this additional information would be eligible for data protection.

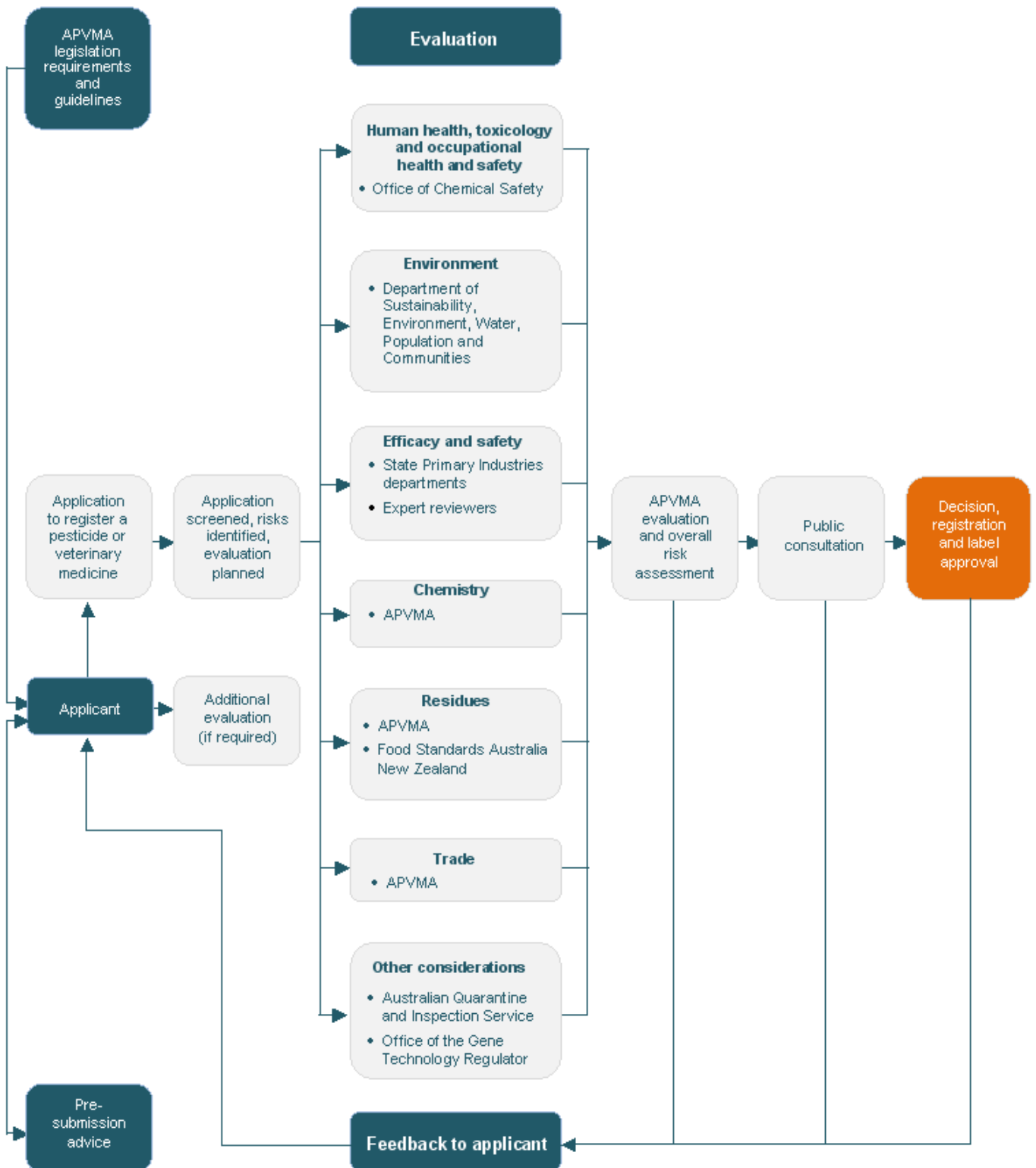


Figure 3: Process map for product registrations

## Evaluation of applications for Good Manufacturing Practice (GMP)

The *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) provides that veterinary chemical products manufactured in Australia must be manufactured in premises to which the APVMA has issued a licence. This provision of the Agvet Code does not apply to agricultural chemical products, as these are exempt under Regulation 59 of the Agvet Code Regulations.

Conditions of product registration require that registrants of veterinary chemical products manufactured overseas provide evidence that the products are manufactured in accordance with a standard at least equivalent to the APVMA's requirements.

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 MLS ensures that veterinary chemical products are manufactured to an approved standard through a quality assurance scheme based on GMP. The MLS applies only to Australian manufacturers of veterinary chemical products, and it requires that anyone involved in any step of manufacture of a veterinary chemical product is appropriately licensed by the APVMA for the step(s) performed, unless the person or product is exempt under the regulations.<sup>6</sup> A licence will be issued after an Australian applicant manufacturer demonstrates compliance with GMP requirements through an initial audit conducted by an APVMA-authorized GMP auditor and by taking any necessary corrective action identified in the audit. A licence remains in force unless it is suspended or cancelled.

The Overseas GMP Scheme ensures GMP-compliance of overseas manufacturers of imported veterinary chemical products. Registrants of imported veterinary products are required to obtain and maintain current evidence demonstrating that the overseas manufacturer of the product complies with a standard of GMP that is at least equivalent to the *Australian Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007* and the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products*. This evidence is required upon application for registration and thereafter provided on request by the APVMA as a condition of registration.

This Cost Recovery Discussion Paper proposes a number of changes to the current licensing arrangements for the MLS Scheme. These are discussed in Section 3.

The main costs incurred by the APVMA in maintaining the GMP-compliance assessment schemes are in the initial assessment of the MLS licence application, consideration of an initial audit report to decide whether a licence should be issued in the first instance, and consideration of subsequent audit reports. For imported products, costs are incurred with the initial and ongoing assessments of evidence of GMP compliance of the overseas manufacturer. Both domestic and foreign manufacturers are required to undergo regular audits by APVMA authorised auditors.

## New Continuation Scheme (re-registration scheme)

The initiatives under the Reform Agenda introduce a Continuation Scheme (re-registration) to systematically consider the ongoing safety of approved active constituents and registered chemical products. It is intended that the entire inventory would be subject to continuation consideration across a 15-year cycle. Approvals of individual active constituents and registrations of chemical products will

---

<sup>6</sup> Regulation 72A of the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

expire every 7-15 years, at a date determined by the APVMA. The expiry dates will be based on risk and will be publicly available. Registrants will need to apply for their approval/registration to be continued and if no application is received the registration / approval will expire and the product will need to be removed from the marketplace.

The Continuation Scheme's fee component relates to the technical and administrative tasks of evaluating the application. If the result of the application is that the product needs to undergo a chemical review, then the chemical review will be funded in accordance with the standard chemical review framework which is funded through the annual fee.

Whilst the continuation scheme will commence in 2012–13 it will take 2 years to become fully operationalized. The costings of the continuation scheme is shown at Table 25.

## Certificates of Export

Before accepting exports of a chemical product from Australia, many countries require an assurance from the government authority responsible for approving the sale of the chemical product in Australia that the export chemical is suitable for supply and use. A Certificate of Export for a chemical product is a document that provides information about an agvet chemical product, a manufacturing site, or an active constituent for export.

Section 69D of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* gives the APVMA the legislative power to issue a certificate for the purpose of exporting a chemical product. An exporter can apply for a certificate for any agvet chemical product that is to be exported. Full cost recovery currently exists for Certificates of Export.

## Consents to Import

It is an offence to import an unregistered product or an unapproved active constituent into Australia unless it has been exempted from the provisions of the Agvet Code or the importer has obtained a Consent to Import from the APVMA.<sup>7</sup> Exemption from the provisions of the Agvet Code may apply under special limited circumstances, for example if an APVMA Permit covers the activity.<sup>8</sup>

The APVMA assesses applications for Consent to Import to regulate the entry of unregistered products and unapproved active constituents into Australia. A person who imports an unapproved active constituent or an unregistered product under Consent to Import cannot on-supply to other parties in Australia unless a permit specifically allows for such action. The APVMA does not currently charge a fee for consents to import. The APVMA believes that charging a fee for consents to import will act as a disincentive to applications. This would hinder the effectiveness of APVMA compliance activities aimed at preventing the importation of unapproved or unregistered active constituents or products. It is appropriate therefore to recover these costs through the levy.

7 Section 69(B) of the *Agricultural and Veterinary (Administration) Act 1992*.

8 The APVMA has capacity to issue permits to use agricultural and veterinary products in ways that differ from the information set out on the approved product label.

## 2.3 Monitoring ongoing compliance with regulations

### Good Manufacturing Practice compliance audits

As a condition of a licence, manufacturers are required to undergo regular audits by APVMA-authorized GMP auditors at their own expense. GMP audit costs are paid directly by the manufacturer to the external auditor. These costs are therefore excluded from the APVMA's cost recovery arrangements.

### Hormonal Growth Promotant Scheme

The APVMA is responsible for the control of supply of Hormonal Growth Promotants (HGPs) within the National HGP Control and Monitoring System managed by the Australian Quarantine and Inspection Service. The system was introduced in 1993 in response to demands by the European Union (EU) for assurance that meat and meat products from Australian cattle were not treated with HGPs.

It is illegal for a person to sell or supply HGPs unless they have a valid notification number issued by the APVMA. To remain valid, the notification number must be renewed annually through payment of relevant fees to the APVMA. The Agricultural and Veterinary Chemicals Code Regulations 1995 require suppliers and retailers to keep particular supply records and provide these records to the APVMA.

Historically, notification number application and renewal fees were payable to the APVMA and then forwarded to state and territory governments (NRS members) with no fee revenue retained by the APVMA. More recently the APVMA is retaining the HGP notification number application and renewal fees to assist in funding the ongoing APVMA administration of the scheme.

Adhering to the requirements of the National HGP Control and Monitoring System, and in particular accounting for every dose of HGPs through accurate records, ensures that Australia's good trading reputation with the EU is maintained. Retailers also benefit from the HGP Scheme through the issue and maintenance of HGP notification numbers, which allow them to sell or supply HGPs. Such products are attractive retail items in the rural sector.

In early 2011 the Biosecurity Services Group – Food Division of DAFF advised the APVMA that in their view the specific regulations governing the HGP Open Scheme was no longer required to sustain European Market (EU) access. DAFF is working with other interested stakeholders to confirm wide concurrence that full reliance on the closed EUCAS system, in preference to the HGP Open Scheme, is appropriate which may then lead to a formal recommendation to rescind these specific HGP regulations.

### Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products

The Quality Assurance Scheme for Agricultural Active Constituents (the Ag QA Scheme) was launched in 2004 as a mechanism by which the APVMA could ensure that all active constituents, and ultimately the products that are formulated from them, are manufactured according to evaluated processes and meet the standards approved by the APVMA at the time of registration.

The Ag QA Scheme utilises *Conditions of Registration* that refer to standards for active constituents which set out the purity of the active constituent and the maximum allowable impurity level. The *Conditions of Registration* for agricultural chemical products underpin the scheme. The conditions include requirements for record keeping by the registrant. These conditions ensure the ongoing quality of the active constituent in the final product, and place a responsibility on the product registrant to ensure that each batch of the active constituent used in the final product meets the approved standard for that active

constituent. The APVMA has conducted specific data call-ins, and onsite visits of agricultural product formulators to monitor compliance with the *Conditions of Registration*.

The Ag QA scheme has been an important and useful tool in strengthening industry practices in overseeing the sourcing of raw materials and their use in the manufacture and formulation of agvet products. It is planned to incorporate the core elements of targeted record auditing and regular chemical active constituent quality testing into the APVMA's wider market surveillance and compliance function. Accordingly, it is no longer considered appropriate to separately and specifically recover the cost of the scheme from participants. The costs will be recovered through the new Annual Fee(s).

The Ag QA Scheme was reviewed in 2008–09 as set out in the 2004 Regulation Impact Statement for the scheme. The outcome of this review is expected to be finalised in early 2012.

### Adverse Experience Reporting Program and Chemical Review

The Adverse Experience Reporting Program (AERP) is the main mechanism for the APVMA to receive and consider stakeholder and public feedback on adverse experiences relating to the use of registered agricultural and veterinary chemicals. The AERP provides post-registration surveillance loops that help facilitate responsible marketing and management of registered agricultural and veterinary chemicals throughout their life. The objectives of the AERP are to provide the APVMA with feedback about the quality, safety and efficacy of registered agricultural and veterinary chemicals in the field. This information helps to ensure that the APVMA's registration decisions are appropriate. The programs help promote and maintain public confidence in the NRS.

The APVMA conducts comprehensive reviews of registered agvet chemicals under its Chemical Review program when the APVMA has concerns about the adequacy of the basis of an existing registration or approval in the marketplace. The purpose of a review is to ensure that chemicals do not pose unacceptable risks to human health and safety, the environment or trade.

A fee-for-service for all registrants whose chemicals are under review would be problematic for these reasons:

- it would be difficult to determine costs for any particular review before the review was completed because the scopes of reviews vary and the complexity of the work undertaken depends on the data provided, as well as other factors including use patterns and sales volumes.
- adverse experience reporting and reviews can occur even if the registrant has adhered to all the conditions of registration.
- the re-examination of a chemical as a result of reports of adverse experiences or review could result in a requirement for further studies or data to be generated and the potential for restrictions on the use of the chemical. In these circumstances, charging a fee to the registrants of products in addition to requesting new studies is likely to exacerbate any difficulties the registrants face as a result of the adverse experience or review of the product.

It is also noteworthy that, while specific chemicals are identified through the AERP and the Chemical Review, any agvet chemical could potentially be the subject of APVMA actions through these programs.

Costs for the AERP and Chemical Review are currently recovered through the levy. Although these programs potentially affect all chemical products and all end users, the APVMA believes that a levy is not the most appropriate mechanism for cost recovery as wholesale sales values are not directly related to these activities.

It is proposed that the recovery of the costs of the AERP, Chemical Review and other post-market activities (but not continuation) should occur through an annual fee. An annual fee would also increase the transparency of this aspect of chemical regulation. Finally, an annual fee incorporating these costs will allow a drop in levy rates to occur.

## 2.4 Investigation and enforcement

The APVMA assesses and investigates claims that agvet chemicals may not be compliant with the requirements of Australia's agvet chemicals legislation. This includes advertising claims that are contrary to the legislation. The APVMA also audits market authorisations, conducts market surveillance, and monitors chemical production in Australia. The overall costs can be accurately determined and an annual fee is administratively simple to collect. Cost recovery is appropriate for investigation and enforcement because charging is consistent with policy goals, and it is efficient and cost effective. Cost recovery therefore appears to be most appropriately undertaken through the annual fee(s).

## 2.5 Information activities

While the APVMA's functions under s.7 (1A) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* are quite broad, the actual information activities involved are integral to maintaining and enhancing the regulatory arrangements. The APVMA provides information on agvet regulatory arrangements through the APVMA website, corporate publications, consultative committees, and presentations and seminars. The provision of this information to stakeholders enhances engagement and raises industry standards in general, and these lead to better outcomes.

The APVMA's policy development and parliamentary servicing functions (such as Senate Estimates hearings, answers to Questions on Notice and ministerial briefings) are integral to the effective management of the NRS and are therefore appropriate and efficient to include in cost recovery.

The APVMA considers that the public good characteristics of its information activities are not significant enough to make it desirable to charge for these products. Given that the agvet chemical industry benefits through the provision of information on agvet regulatory arrangements and the effective management of the NRS, the costs of these activities should be recovered as overheads attributed to the service delivery sections of the APVMA.

## 3 DESIGN AND IMPLEMENTATION OF REVISED COST RECOVERY ARRANGEMENTS

### 3.1 The need to review cost recovery arrangements

Government policy requires agencies to review cost recovery arrangements at least once every five years. Factors that will influence the 2012 CRIS include the following:

- a mechanism to recover the costs of operating a new Continuation Scheme introduced as part of the Reform Agenda
- a commitment to further improve timeframe performance as efficiencies flow from the Reform Agenda
- a possible increase in compliance and enforcement resourcing
- the need to return \$2 million of funding provided as part of the Reform Agenda to government in future years
- the need to realign the cost recovery for product evaluations with the policy position of collecting 40 per cent of the cost of assessment at the time of application (the actual cost recovery rate is currently averaging 24.7 per cent for product applications)
- a mechanism to recover the cost of processing some types of applications for active constituents
- the merit of introducing more equity through direct charges for some activities where this can be established (in accordance with Cost Recovery Guidelines)
- the need to review cost recovery arrangements for the GMP licensing scheme and the compliance assessment schemes (including the MLS).

### 3.2 Improving the existing arrangements

The existing cost recovery arrangements documented in the 2005 CRIS should be improved. This is evidenced by the following:

- cost recovery for product evaluations is well below the 40 per cent recovery rate for upfront application fees (the cost recovery rate is currently averaging around 24.7 per cent with the remainder recovered through the levy)
- MLS licence fees that have resulted in under-recovery of GMP activity costs in the order of \$1.1 million (in 2007–08)
- there is currently a high reliance on levy revenue that, because of fluctuations in agvet chemical sales due to climatic variations, results in large fluctuations in the APVMA's revenue base.

Table 10 lists the history of costs incurred compared to revenue for applications for registration and approval during the three years since the last review.

**TABLE 10: HISTORY OF APPLICATION FEE REVENUE AND REGISTRATION AND APPROVAL EXPENSES**

	2007-08	2008-09	2009-10	2010-11
Application fee revenue (\$)	3 241 865	3 404 117	3 201 131	4 233 912
Registration expenses (\$)	17 297 228	18 261 343	18 662 366	19 118 727
<b>Cost recovered (%)</b>	<b>18.74</b>	<b>18.64</b>	<b>17.15</b>	<b>22.15</b>

*Note: the target rate of recovery is 40 per cent. The balance of registration expenses was recovered through the levy on wholesale product sales.*

As noted above, application fees are currently only recovering around 22.15 per cent of the cost of performing the services (as opposed to the 40 per cent policy target). This is primarily because the fees are not indexed. Without indexation, the fees will become progressively more non-reflective as time goes by.

The APVMA proposes to return all application fees to the SWG 40 per cent target level. To cushion the increase, it could be returned to 40 per cent target in two phases:

- Phase one—an increase of all fees to 30 per cent of the cost of undertaking the associated activities in the first year (from 1 July 2012)
- Phase two—an increase of all fees to 40 per cent of the cost of undertaking the activity in the second year (from 1 July 2013).

### 3.3 Legal requirements for the imposition of charges

The APVMA's fee structure is authorised by a number of provisions in numerous pieces of legislation relating to the APVMA and agvet chemicals.

Application, annual and some other fees (such as the assignment of HGP notification numbers and their renewal) are provided for in the Agricultural and Veterinary Chemicals Code Regulations 1995 made under the Code Act. Fees for the MLS are also provided for in the Agvet Code Regulations.

The Code Act also contains a schedule—the Agricultural and Veterinary Chemicals Code (the Agvet Code)—which contains the detailed operational provisions for most of the APVMA's powers and activities.

The Agvet Code Regulations contain a table in a schedule (Part 2 of Schedule 6), which sets out 25 separate categories of application and the fee for each category. The Schedule 6 table provides that some application fees are to be determined by the 'modular assessment fee' determined in accordance with Schedule 7 of the Agvet Code Regulations.

Schedule 7 provides for 12 broad modules to be applied to applications for which the 'modular assessment fee' is to apply. For many of the modules, one of several levels or types may apply with varying fees for the different levels. Which particular category or module is to apply to any particular application is more fully detailed in legislative instruments made by the APVMA in accordance with its powers under sections 164 (1A) and 165(1A) of the Agvet Code.

The APVMA has made the following three legislative instruments to date in relation to fees and timeframes: the *Agricultural and Veterinary Chemicals Code Instrument No. 1 (Application Fees) 2010*; the *Agricultural and Veterinary Chemicals Code Instrument No. 2 (Modular Assessment Fees) 2010*; and

the *Agricultural and Veterinary Chemicals Code Instrument No. 3 (Assessment Periods for Applications where Additional Information is Submitted Voluntarily) 2008*.

The levies payable on the sale of agvet chemical products are authorised by the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995* made under that Act. The levies are a tax, which requires a separate tax Act. The levy is imposed by the *Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994*; the *Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994*; and the *Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994*.

Fees for export certificates are provided for in the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* made under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. Consents to Import are also authorised by the Administration Act.

### Which issues should any legislation address?

The Guidelines advise agencies to consider the level of specific guidance to be included in legislation or any regulations attached to legislation. Matters to be considered include:

- whether legislation specifies the detail (such as level and rates) of the cost recovery charges or provides guidance on the desirable characteristics of the charges
- balancing the level of certainty with the need for flexibility
- if detailed guidance is to be included in the legislation, whether this is consistent with constitutional requirements.

The legislation already provides the framework to enable implementation of the cost recovery charges. The proposed changes will amend specific details such as the amounts charged for fees, or relevant dates, without altering the intent or context of the legislation. The key exceptions include:

- the ending of current MLS licence fees and the implementation of the new licence fee structure
- proposed waiver of outstanding MLS licence fees
- provision for the indexation of a number of fees (see next section).

### 3.4 The introduction of indexation

The APVMA proposes to index all fees annually (annual fee, application fees for registration and approval Certificates of Export and HGP notification number and renewal) to ensure that fees remain cost reflective over time.

Indexation rates will be based on 75 per cent of the Wage Price Index (WPI) (annual change in WPI trend for the public sector) and 25 per cent of the Consumer Price Index (CPI) (annual change in all groups CPI, weighted average of eight capital cities), reported for the December quarter by the Australian Bureau of Statistics. The indexation rate is more heavily weighted to the WPI because the APVMA spends more on salaries than on supplies. The APVMA is subject to CPI increases and wage cost increases through service level agreements with other agencies—a mechanism is needed to ensure fees remain cost reflective over time.

It is proposed that indexation for application fees applies from 1 July 2014 one year after fees have returned to 40 per cent of the cost of the assessment. Indexation for other fees and charges will apply from 1 July 2013 (12 months after the commencement of any new cost recovery arrangements).

Where a material amendment is made to any of the fees (other than indexation at the defined indexation rate), a specific CRIS will be prepared for the new fee in accordance with the Guidelines.

The proposed indexation measures, if implemented, will be put in place through additional provisions in the Regulations or by legislative instrument made by the APVMA taking into account the application of indexation, rounding and any possible negative outcomes. The APVMA will publish a table specifying the exact fees derived from indexation in the April *Gazette* each year.

Fees will be rounded to the nearest five dollars. In the event that the calculated indexation rate is a negative number, the APVMA will leave fees at the previous year's level. In the following year, the APVMA will factor the negative year's rate into the calculation.

### 3.5 Registration and approvals

Key components of possible changes to application fees discussed in this paper include:

- moving all application fees to at least 30 per cent cost recovery from 1 July 2012 and 40 per cent from 1 July 2013, with the remainder of the costs to be recovered from the levy
- introducing a new Fee for Continuation set at 40 per cent of the cost of administrative and technical evaluation and assessment of applications for Continuation;
- applying 100 per cent cost recovery for approval of an active constituent (Category 17 only)
- fees for permits to remain largely unchanged (only indexation will be applied) where it can be documented that an increase in expenses have occurred for this activity
- maintaining a nil fee for Category 22 (emergency use permit) applications (cost to be recovered through the levy)
- indexing all application fees each year on the basis of 75 per cent WPI and 25 per cent CPI to ensure fees are cost reflective over time from 1 July 2014.

It is proposed to maintain the modular fee structure and the APVMA will establish a recovery rate of 30 per cent of the cost of the evaluation from 1 July 2012 and then 40 per cent of the cost of the evaluation from 1 July 2013.

These could be subject to indexation from 1 July 2014 as previously discussed. The remaining evaluation costs could be recovered through the levy (60 percent from 1 July 2013). Exceptions to this are Category 17 applications discussed below.

#### *Basis of charging—fee or levy*

While analysis of registrations and approvals suggests that a fee is the appropriate means of cost recovery for these activities, historically the costs of registrations and approvals have been recovered through a combination of application fees and the levy, with most of the costs recovered through the levy.

The existing cost recovery arrangements incorporate different levels of cost recovery through the application fee depending on whether the evaluation involves registration of a product—40 per cent cost

recovery through the application fee for categories with a technical evaluation and 100 per cent cost recovery for administrative services. Application Categories 13 and 22 have nil fees (discussed below).

The SWG determined that fees are appropriate for registrations and approvals. However, it recommended that a nominal fee of 40 per cent of the cost of assessing applications for approvals and registration be paid as an application fee, with the remainder to be recovered across the life of the product through the levy collected from companies at the point of wholesale sale and presumably transferred to the users of agvet chemicals through the pricing mechanism. The SWG considered that a higher level of cost recovery through the application fee would be a significant disincentive for new products and innovation into the market, particularly in the case of small businesses, niche products, and chemical products that have a low value of sales.

In previous cost recovery reviews, stakeholders have argued for changes to the balance between fees and the levy. In previous reviews it has not been possible to reach consensus across stakeholders on the level of split between application fees and levy.

The APVMA notes the current high reliance on levy income (in 2010–11, 66 per cent of the APVMA's income was derived from the levy [ignoring one-off Reform Agenda funding]) and believes that a reduction of this reliance on the levy is both sensible and appropriate.

#### Pre-application guidance (for product or active registration)

The Better Regulation of Agricultural and Veterinary Chemicals reforms introduce, in proposed amendments to the Regulations, a fee for the provision of application guidance to applicants by the APVMA. A possible fee structure for this activity is outlined below. It comprises two discrete aspects for product and active registrations (but not permit applications):

1. A fee of \$350 charged for the provision of advice to applicants. The fee includes written guidance in response to an applicant's queries for their application, guidance on completion of the necessary application form(s) and advice on data requirements. Where the APVMA believes it is necessary, this response may be provided through a meeting or telephone conversation (as determined by the APVMA). The APVMA's response to the query will be considered to conclude the service. Any further discussion of the query will attract an additional fee (see below).

Where the query relates to a future application, and the applicant subsequently submits an application directly related to the advice, only the initial fee (\$350) will be refunded against the cost of the application.

2. A fee of \$350 charged for each and every subsequent request for guidance (on completion of the necessary application form). This additional fee is not refunded.

#### Fee Rebate

The APVMA is examining the possible introduction of new arrangements to automatically refund to applicants 10 per cent of the cost of the original application fee if the application is not finalised within the specified statutory timeframe.

The rebate acknowledges the commercial impact of late market authorisation and moving to enhance APVMA compliance to statutory timeframes is an explicit government policy purpose under the Better Regulation Reforms. Rebates could possibly be refunded to applicants automatically. This initiative would demonstrate a commitment to meet statutory timeframes.

### *Category 13 applications*

Category 13 applications are for minor changes to particulars or conditions of registration or listed registration or label approvals that are required by the APVMA. They represent approximately 5 per cent of new applications received each year. The changes are commonly driven by changes to technical standards by government authorities or international bodies as a function of the health and safety standards required for continuing in the market.

Charging for these applications would be inconsistent with policy goals as it could significantly increase the cost of compliance and enforcement for the APVMA. It could be expected that charging for these minor variations could create incentives for firms to avoid making the application, which would eventually mean increasing the costs of enhancing compliance activities for the APVMA to be sure revisions to manufacture etc were being made, and in the shorter term reducing the current accuracy of APVMA records as to variations of products under APVMA registration, which could detract in the level of community confidence in the regulatory framework.

In accordance with SWG guidance, the cost of this post-market activity should be recovered entirely through the levy with the existing nil application fee being retained.

### *Category 15 and 16 applications (new active constituent)*

Application Category 15 is for a new active constituent that requires a full assessment. This application category is currently met by both a fee (40 per cent) and a levy (60 per cent) component. These applications are generally linked to a product application.

Only a very small number of Category 15 and Category 16 applications [to only approve an active constituent (and not linked to the registration of the product)] are received by the APVMA each year. In the last four years, only four Category 15 and three Category 16 applications were received. Once the application has been approved, data protection applies for a period of seven years.

Recovering the costs of these applications through the levy is consistent with policy goals as these applicants are innovators who introduce new chemistry into the Australian market. If this product category were recovered at 100 per cent of the cost of processing the application, it would stifle innovation.

Therefore it is proposed to continue the current arrangements where the small number of Category 15 and Category 16 applications are met by the levy. The levy will fund the remaining 60 per cent through the associated exclusivity of the product. Higher levels of cost recovery through the application fee will be a disincentive for the introduction of new actives into the market.

### *Category 17 (imaged or 'me too' active constituent applications)*

Application Category 17 is for approval of an active constituent that requires less than a full assessment but does not require a toxicological assessment. Generally these applications are for imaged active constituents or 'me too' applications. During the past six years, a total of 436 Category 17 applications have been received. For generic active applications, there can be multiple approval holders that are not necessarily associated with registered products that are sold (while an application to register a product must nominate where the active constituent is sourced, once the product is registered, the active can be sourced from any of the approved sites).

Unlike applicants to Categories 15 and 16, Category 17 applicants are not innovators but rather seek to copy existing approved active constituents once the period of data protection has ended. Unlike Category 15 and 16, the recovery of 100 per cent of the cost of processing the application will not stifle innovation. These applications therefore should be recovered at 100 per cent of the cost of processing the application.

#### *Category 18 (variation of particulars for an active constituent applications)*

Category 18 applications are for varying particulars or conditions of an approved active constituent. The applications are currently met by both a fee and the levy (60 per cent of the cost of processing the application is funded from the levy). Recovery of the costs of these applications through the levy is consistent with policy goals as the full cost recovery would reduce the number of applications lodged and thus stop applicants from advising the APVMA of changes to their approval. The flow-on effect is that the APVMA's Register of Approved Active Constituents will be more accurate under these arrangements.

#### *Category 19-21 (permits)*

The 2005 CRIS documented a fee of \$320 for Minor Use permits (Category 21) (increased to \$350 in 2010). In line with the cost increases, the fees will be indexed annually from 2013-14 onwards where it can be documented that expenses have increased commensurate.

Minor Use permits allow the use of an agvet chemical in a manner that is not on the registered product label and that may otherwise be illegal in some jurisdictions. Often, Minor Use permits are issued for the use of an agvet chemical in small, emerging or niche industries. These industries typically include horticultural crops, minor cereal grains, oilseeds and pulses and small livestock industries.

The permit applicant is usually a grower or a grower organisation that requires chemicals for very specific uses, and these are most commonly where the registrant of the chemical has already made a decision that registration of these uses is not commercially viable. If the permit applicant is a grower organisation, the APVMA will typically issue a general permit that allows the particular use without restrictions on who can use the agvet chemical in a prescribed way. Data protection provisions are structured to encourage industry preference away from Minor Use permits—preferring instead product registration—by providing longer periods of data protection for applicants that include Minor Uses as part of an initial application. Information provided to the APVMA in support of a Minor Use permit does not receive data protection.

Growers and grower organisations (as permit approval holders) pay the costs of generating any required data in support of a Minor Use permit and the permit fee. These costs cannot be recouped through product sales by growers in the same way that registrants are able to do. It is considered that the fee should be a contribution to cost of assessment for a Minor Use permit.

The APVMA proposes to retain the 2005 approach of a fee for Minor Use permits. The balance of costs will be recovered through the levy on wholesale sales of registered products.

Indexation if approved should be applied on all Minor Use permit fees, as with all other application fees. By linking fee increases to publicly reported WPI and CPI data, only actual increases in costs will be recovered. This approach is in line with the APVMA and government policy objectives of enabling access to safe and effective chemicals with appropriate regulation to meet Minor Use needs.

It is proposed that Commonwealth and state/territory government agencies pay the usual fee for permits where this is associated with a use that provides a significant commercial benefit to that organisation or an agent of that organisation. However, there will be an exemption from payment of fees where the Australian, state or territory governments apply for a permit in support of their core business.

Activities not considered to be fee exempt would include those activities where a profit is attracted from investment and/or the service provided. This would include activities such as:

- Commercial state forestry operations
- Commercial research activities undertaken by departments. This would encompass activities that develop new technologies either through contract research or alone and where those activities attract intellectual property of a value that may later be sold for profit or are conducted on a fee for service basis.

These arrangements are already provided by r.70(6) of the Agvet Code Regulations. It is not intended to make any changes to these arrangements.

#### *Category 22 (Emergency Use permits)*

Category 22 (Emergency use permits) currently have a nil fee and this will remain unchanged. The cost of these permits will be collected through the levy.

#### *Category 23 (Research permits)*

Research permits allow the use of agvet chemicals in technical trials and to generate information in support of a potential application for registration or a permit. As these permits are for specific uses with private benefit, there is no opportunity for 'free riding' from the permit. In addition, the assessment and issue of research permits is commercial in confidence.

As the information generated through research conducted under this type of permit can later be used to obtain registration (whereupon the registrant may recoup application fees through product sales as well as attract data protection), the applicant should be charged for the cost of assessment. However, if and when a formal application for registration is lodged, the applicant would not be charged for the same assessment twice.

In terms of a fee, the same arguments as for applications and registrations are relevant, and it is appropriate to charge a modular fee based on the level of work required.

#### *Evaluation of applications for Continuation (re-registration)*

As noted previously, the costs associated with initial applications for registrations and approvals have been historically recovered through a combination of application fees and the levy.

The SWG recommended that a nominal fee of 40 per cent of the cost of assessing applications for approvals and registration be paid as an application fee, with the remainder recovered across the life of the product through the levy collected from companies at the point of wholesale sale and presumably transferred to the users of agvet chemicals through the pricing mechanism. In setting the split at 40 per cent of the cost of assessing the application, the SWG considered that higher level of cost recovery through the application fee would be a significant disincentive for new products and innovation into the market.

Products applying for re-registration have already been through the initial registration process, and thus there are no arguments that support a split payment based on encouraging innovation.

In designing a fee structure, it is important to not provide a price incentive that might encourage continuation applicants to 'game the system' by avoiding continuation. For example, if the cost of continuation is higher than the cost of initial registration, registrants could intentionally allow their product registration to lapse and then reapply for registration. The fee for a Category 8 'repack' is currently \$595.

A registrant could avoid the continuation scheme entirely by intentionally allowing a product(s) registration to lapse and then apply for a \$595 Category 8 re-pack. In this way registrants could avoid the higher potential continuation costs together with the scrutiny that the continuation process encompasses.

Accordingly, it is proposed to retain a split payment to ensure that the cost of continuation is no more than the cost of initial registration. Table 11 below provides information on the cost components to be included in charges for registration and approvals. A summary of the contributions of individual sections to the costs of each application category and module is available in Appendix C.

**TABLE 11: COST COMPONENTS OF REGISTRATION AND APPROVALS (2010-11 COSTS)\***

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: REGISTRATION AND APPROVALS			
Employee expenses	Technical and administrative assessment costs	Direct cost	7 380 233
Suppliers	Outsourced activities—scientific assessment services undertaken by external agencies	Direct cost	3 884 414
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	7 854 080
<b>Total</b>			<b>19 118 727</b>

\*Not including Continuation Scheme

## Evaluation of applications for Good Manufacturing Practice

### *Basis of charging—fee or levy*

As previously discussed the GMP compliance assessment schemes consist of two schemes: the MLS for Australian manufacturers, and the Overseas GMP Scheme for products manufactured overseas and imported into Australia.

The MLS fee structure was not reviewed in the 2005 CRIS. However, the 2005 CRIS included a recommendation that the MLS be specifically included in the terms of reference for the review of cost recovery arrangements in the future.

Under the MLS, the APVMA issues licences to Australian manufacturers of veterinary chemical products once they have satisfactorily passed an audit that proves compliance with the *Agricultural and Veterinary Instrument No. 1 (Manufacturing Principles) 2007* and the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products*. The licence fee is a one-off fee of \$6 600, payable in annual instalments. The annual instalments are spread over four to 40 years, depending on the licence category, the steps of manufacture performed, and other recognised GMP accreditation held. Instalments range from \$165 to \$1 650 a year, and they cease once the total fee of \$6 600 has been paid.

The APVMA issues an average of 22 new licences each year, and cancels an average of 23 licences each year. Licence cancellation may be due to the manufacturer changing sites, changes to the company (legal entity), or because the APVMA imposed the cancellation. When a licence is cancelled, the Agvet Code requires the APVMA to waive any unpaid balance of the \$6 600 licence fee.

The Overseas GMP Scheme does not attract any fees to assess initial or ongoing compliance for imported products or for screening of product applications.<sup>9</sup>

The APVMA investigated a number of proposals to recover the costs of GMP:

- reducing the payment term of the MLS (from four to 40 years) to a maximum of five years
- introducing an annual MLS licence fee
- establishing a levy of 0.15 per cent on the wholesale sale of veterinary medicine products
- introducing a combination of an annual MLS licence fee (between \$1 000 and \$2 000 a year) and a reduced levy on the wholesale sale of veterinary medicine products.

There are legal limitations on changing or imposing additional requirements on existing licence holders. The licences provide a right to manufacture, and this right cannot be limited after a licence has been issued.

In 2010–11, the cost of operating the GMP Section was \$1 396 794. The cash received (through licence fees) over the same period was \$67 098 for the year, leaving a shortfall of \$1 310 467. Furthermore, APVMA cash inflow from licence fees is progressively reducing as more licences become fully paid. At present, about 362 of the 513 MLS licensees have fully paid for their licences.

If the APVMA were to establish another licence scheme with a higher licence fee for new licences for Australian manufacturers, this would require the new licence fee for new Australian manufacturers to be set at about \$50 000 to recover the full annual cost of the GMP compliance assessment schemes.

For these reasons, the APVMA believes that changes should occur to the MLS. It is inefficient, inequitable and financially impractical to use the MLS licence as a mechanism for recovering the costs of the GMP compliance assessment schemes. The current system is inefficient in that it:

- does not recover the cost of activities
- is not cost reflective
- has a high administrative overhead within the APVMA associated with the collection of licence fee instalments, tracking of unpaid balances, sending correspondence, etc.

### Proposed new cost recovery charge for GMP

The APVMA considers that it would be inequitable to recover the costs of GMP from all registrants. It is however possible to charge a specific GMP annual fee that would recover the cost of the GMP scheme from those veterinary companies that participate in the scheme. It is also noteworthy that some veterinary products are exempt from the requirements to be manufactured in premises that have a manufacturing licence (classified as non-GMP veterinary products for the purpose of the CRIS).

It is therefore proposed to introduce a specific annual fee to recover the full cost of the GMP Scheme from those veterinary companies that participate in the scheme. Non-GMP veterinary products would be charged a lesser amount.

---

<sup>9</sup> With the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products

All registered GMP products would pay an equal share towards the costs of the GMP Scheme itself and other post-market activities including investigation and enforcement, Chemical Review and AERP.

MLS licence fees would be abolished and all outstanding liabilities for these fees would be waived. New licences would be issued without charge to the applicant. The cost of GMP will be recovered through the use of a new annual fee which will be payable by all registrants who have products that are required to be formulated at licenced premises. This fee will be specified through an appropriate amendment to the Agvet Code Regulations.

### *Basis of charging—fee or levy*

A fee is appropriate because the applicants can be identified and the costs of the activities are closely linked to the service.

### *Costs to be included in charges*

Table 12 provides a high-level overview of the cost components to be included in charges for the GMP compliance assessment schemes.

**TABLE 12: COST COMPONENTS OF GMP CHARGES 2010-11**

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: GMP COMPLIANCE ASSESSMENT SCHEMES			
Employee expenses	Assessment of MLS licences and imported products with GMP compliance; and management of GMP auditing.	Direct cost	746 983
Suppliers	(GMP audit costs are paid directly by the manufacturer to the external auditor)	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	649 811
<b>Total</b>			<b>1 396 794</b>

### *Outline of charging structure*

A new annual fee model could be developed based on two separate charges for different categories of agvet products, which are calculated on their contribution to the need for the activity. The two categories that are proposed are as follows:

- all agricultural products and non-GMP veterinary products (\$620 in 2014–15): under this category, all registered agricultural products and non-GMP veterinary products pay an equal share towards the costs of investigation and enforcement, Chemical Review and the AERP (excluding the Continuation Scheme costs where a direct fee is applied).
- GMP veterinary products (\$1 115 in 2014–15): under this category all GMP veterinary products pay an equal share towards the costs of investigation and enforcement, Chemical Review and the AERP (excluding the Continuation Scheme costs) and the specific costs of the GMP scheme.

## Certificates of Export

### *Basis of charging—fee or levy*

A direct fee to the users of this service is appropriate because charging is consistent with policy goals, efficient and cost effective to collect.

### *Costs to be included in charges*

Table 13 provides a high-level overview of the cost components to be included in charges for Certificates of Export.

**TABLE 13: COST COMPONENTS OF CERTIFICATES OF EXPORT CHARGES 2010-11**

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: CERTIFICATES OF EXPORT			
Employee expenses	Assessment of compliance with GMP and administrative services	Direct cost	30 789
Suppliers	Not applicable	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	43 161
<b>Total</b>			<b>73 950</b>

## Consent to Import

### *Basis of charging*

In 2010—11, a total of 270 Consents to Import were received. The APVMA believes that charging a fee for consents will act as a disincentive to applications. The APVMA proposes believes there would be merit in maintaining the provision of Consents to Import as a service where there is no direct charge.

### *Costs of Consent to Import activities*

Table 14 provides a high-level overview of the cost components to be included in charges for Consent to Import.

**TABLE 14: COST COMPONENTS OF CONSENT TO IMPORT ACTIVITIES 2010-11**

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: CONSENT TO IMPORT			
Employee expenses	Consent to Import assessment	Direct cost	157 557
Suppliers	Not applicable	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	146 941
<b>Total</b>			<b>304 498</b>

### 3.6 Monitoring ongoing compliance with regulation

All products should contribute to the cost of activities associated with chemical review, monitoring of compliance and AERP as these activities are directly relevant to registrant's responsibility for product stewardship.

#### Hormonal Growth Promotant Scheme

##### *Basis of charging—fee or levy*

Suppliers who apply for a HGP notification number or renewal should pay for the costs of issuing and maintaining these records because this allows them to sell or supply HGPs in accordance with the Agvet Code. A fee is appropriate because the applicants can be identified and the costs of the activities are closely linked to the service.

##### *Costs to be included in charges*

Table 15 provides a high-level overview of the cost components to be included in charges for the HGP Scheme.

TABLE 15: COST COMPONENTS OF THE HGP SCHEME CHARGES 2010-11

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: HGP SCHEME			
Employee expenses	Assessment of new licences, licence renewals, licence withdrawals and HGP audits (including investigations)	Direct cost	51 368
Suppliers	Not applicable	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	47 907
<b>Total</b>			<b>99 275</b>

#### Quality Assurance Scheme for agricultural active constituents and agricultural chemical products (Ag QA Scheme)

##### *Basis of charging—fee or levy*

Since the 2009 draft CRIS the Ag QA Scheme has been included as an ongoing compliance task, and it is no longer considered appropriate to separately and specifically recover the relatively small cost of the scheme from participants. As neither a fee-for-service nor a sales-based levy is appropriate, the cost of the Ag QA Scheme should be evenly spread over the full suite of agricultural chemical products: the most effective collection mechanism is the (ag) annual fee. The levy will provide the balancing funds if the annual fee does not recover the full cost of these post-market activities.

##### *Costs to be included in charges*

Table 16 provides a high-level overview of the cost components to be included in charges for the Ag QA Scheme.

TABLE 16: COST COMPONENTS OF THE AG QA SCHEME CHARGES 2010-11

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: Ag QA SCHEME			
Employee expenses	Audit (record inspections) and testing	Direct cost	88 629
Suppliers	Not available	Not available	Not available
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	82 657
<b>Total</b>			<b>171 286</b>

## Adverse Experience Reporting Program (AERP) and Chemical Review

### *Basis of charging—fee or levy*

Costs for the AERP and Chemical Review are currently recovered through the levy. Although these programs potentially affect all chemical products and all end users, the APVMA believes that a levy is not the most appropriate mechanism for cost recovery as wholesale sales values are not a suitable proxy for the cost driver of this activity.

It is proposed that the recovery of the costs of the AERP (and other post-market activities other than continuation) should occur through an annual fee. An annual fee would also increase the transparency of this aspect of chemical regulation and enable all stakeholders to identify the cost-benefit of the activities. The levy will provide the balancing funds if the annual fee does not recover the full cost of these post-market activities.

### *Costs to be included in charges*

Table 17 provides a high-level overview of the cost components to be included in charges for the AERP and Chemical Review.

TABLE 17: COST COMPONENTS OF THE AERP AND CHEMICAL REVIEW CHARGES 2010-11

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: AERP AND CHEMICAL REVIEW			
Employee expenses	Review work, AERP	Direct cost	999 842
Suppliers	Outsourced activities—scientific assessment services by external agencies	Direct cost	492 383
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	919 926
<b>Total</b>			<b>2 412 151</b>

### 3.7 Investigation and enforcement

#### *Basis of charging—fee or levy*

It is proposed that the cost of investigation and enforcement should be borne by registrants and approval holders because it is their responsibility to supply a product that is registered or approved and that complies with the conditions of registration or approval.

As neither a fee-for-service nor a sales based levy is appropriate, the cost of the program could be evenly spread over the full range of chemical products and the most effective collection mechanism appears to be the annual fee.

#### *Costs to be included in charges*

Table 18 provides a high-level overview of the cost components to be included in charges for investigation and enforcement.

TABLE 18: COST COMPONENTS OF INVESTIGATION AND ENFORCEMENT CHARGES 2010-11

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST (\$)
ACTIVITY: INVESTIGATION AND ENFORCEMENT			
Employee expenses	Non-compliance report processing, product recalls and investigations	Direct cost	1 080 373
Suppliers	Not applicable	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	1 007 579
<b>Total</b>			<b>2 087 952</b>

### 3.8 Information activities

The costs of information activities were calculated as non-service delivery activity costs (overheads) in the ABC study. All overhead costs were aggregated and allocated to the ten sections (Pesticides Registration, Pesticides Residues, Pesticides Chemistry, Chemical Review & AERP, Veterinary Registration, Veterinary Residues, Veterinary Chemistry, GMP, Application Management and Enquiries, and Compliance) in proportion to the number of staff in each section.

Fees and charges for specific activities such as extracts and copies of information from the Record of Approved Active Constituents for Chemical Products and Register of Agricultural and Veterinary Chemical Products will be reflective of the processing and materials costs of the activity and will be indexed.

### 3.9 The annual fee

Two categories of annual fee are proposed:

- **Annual Fee for Agricultural Products and non-GMP Veterinary Products.** This involves the recovery of costs of investigation and enforcement, the Ag QA Scheme, Chemical Review, the AERP

(but not continuation). This would reduce reliance on the levy as these activities are currently largely funded through the levy. The APVMA considers payment of the annual fee as a contribution to the cost of maintaining a sound regulatory environment; the decision of maintaining zero sales products on the register rests with the registrant. The APVMA considered that it would be inequitable to recover the cost of GMP from all registrants, therefore these costs will be recovered from GMP veterinary product registrants only. Another consideration was that some veterinary medicine products<sup>10</sup> are exempt from the requirements for manufacturers in premises that have a manufacturing licence (classified as non-GMP veterinary products for the purpose of the proposed cost recovery arrangements).

- **Annual Fee for Veterinary Products that Participate in the GMP Scheme.** This involves the recovery of costs of the above, but it includes a surcharge for the recovery of specific costs to fund the associated with the GMP Scheme.

The APVMA is aware that there are some circumstances where it may be appropriate to apply a concession annual fee. In particular there are some very low selling, but important veterinary products that must be maintained. Accordingly, the APVMA proposes to introduce arrangements to allow registrants to apply for a concessional annual fee of \$430 where the following circumstances can be proven:

- the product is on the market and being sold
- there are a limited number of alternative products
- sales are very low.

It is important to highlight that, because the reduced levy rates would not apply until 2013–14, it would be necessary to phase in the implementation of the annual fee. To this end, a combination of the annual fee and levy could be applied to cover the cost of post-market activities in 2012–13 (the annual fee would remain at \$430), and the new annual fee model would be introduced in 2013–14. The annual fee required to fund the cost of the activities as described in this section also depends on an estimate of the number of products that will renew their registration. To soften the impact of funding the cost of the GMP scheme via the annual fee charges on GMP veterinary products, it is proposed that a 20 per cent discount is given to these products in 2013–14. The fee will be 100 per cent of the cost in 2014–15 onwards.

The APVMA proposes that both annual fees are indexed each year based on 75 per cent WPI and 25 per cent CPI (reported in December of the previous year) to ensure fees are cost reflective over time. Annual fee revenue elements are shown in Table 19.

---

<sup>10</sup> Regulation 59 of the Agvet Code Regulations provides that veterinary chemical products that are homeopathic preparations more dilute than 1/1000 of a mother tincture, skin cleansers or shampoos, coat conditioners, equine hoof protectants or sheep-branding substances are exempt from the requirements for manufacturers in premises that have a manufacturing licence.

TABLE 19: 2014-15 ANNUAL FEE REVENUE AND ACTIVITIES FUNDED BY ANNUAL FEES

ANNUAL FEE	ALL PRODUCTS	PLUS	PREMIUM PAID BY GMP PRODUCTS	TOTAL
<b>REVENUE</b>				
Component of annual fee (\$)	620		495	
Estimated number of products	10 291		3 447	
Revenue: annual fee (\$)	<b>6 380 420</b>		<b>1 706 265</b>	<b>8 086 685</b>
<b>EXPENSES</b>				
Investigations and enforcement, AERP and chemical review (\$)	6 497 452			
GMP compliance (\$)			1 602 840	
<b>TOTAL (\$)</b>	<b>6 497 452</b>		<b>1 602 840</b>	<b>8 100 292</b>

Late payment of the annual fee currently attracts a penalty of \$50 per product to cover the additional administration costs. The APVMA proposes that this penalty continue however the amount would be increased to \$100.

### 3.10 The levy

The APVMA proposes to retain the levy model that has previously operated until the fundamental review is completed. The tiers decrease the relative level of contribution by low-sales products to recover the shortfall in the cost of assessing applications whilst reducing the contribution by high sales products to more reasonable levels. Key components of the levy revenue include:

- maintaining the levy as the balancing factor (note reliance on the levy is reduced if activities such as the Chemical Review, AERP and GMP are funded through the annual fee instead of the levy)
- lowering the levy rate (rates are shown at Table 20).

The increase to the annual fee(s) would allow changes to be made to the tiered levy model is as follows. The proposed levy rates for 2013–14 (based on sales from 2012–13) is shown below.

TABLE 20: LEVY RATES

LEVY PAID IN	2011-12	2012-13	2013-14	2014-15	2015-16
BASED ON SALES DURING	2010-11	2011-12	2012-13	2013-14	2014-15
Levy tier 1	0.80%	0.75%	0.57%	0.57%	0.57%
Levy tier 2	0.45%	0.43%	0.30%	0.30%	0.30%
Levy tier 3	0.30%	0.29%	0.15%	0.15%	0.15%

Tiered levy thresholds are based on:

- no levy is collected for annual product sales up to \$5 000 (as it is not efficient to do so)
- levy tier 1 rate for annual product sales up to \$1 000 000
- levy tier 2 rate for additional annual product sales between \$1 000 001 and \$5 000 000
- levy tier 3 rate for additional annual product sales greater than \$5 000 000.

The increase in application fees and the use of the annual fee(s) to recover most post-market activities would allow the levy rates to be reduced in the proposed levy rates. The levy rate changes would be implemented by an amendment to the rates specified in r.6A(2) of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995*.

An additional charge currently applies for late payment of the levy: (i) \$200 for unpaid levy less than \$10 000; or (ii) \$400 for unpaid levy greater than \$10 000. There is an additional penalty for understatement of disposals. Both of these penalties would continue.

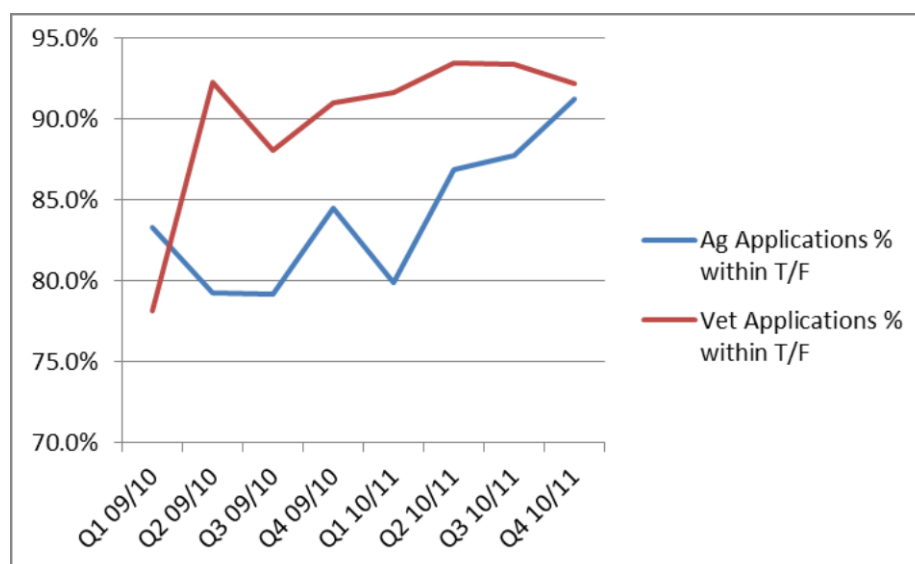
### 3.11 Further improving timeframe performance

#### Timeframe performance

Timeframe performance during the period 2009 to 2011 is shown in Figure 4 below. The graph illustrates how timeframe performance can be improved as a result of productivity improvements. The improvements reflected in Figure 4 are primarily the result of new labelling requirements introduced in July 2010 whereby the APVMA was no longer required to assess elements of an agvet product label such as colour, presentation, logos, marketing information, warranty and other company information. The new labelling requirements limited the APVMA's consideration to only those matters prescribed in the legislation and regulations (the 'relevant particulars').

The improvement in timeframe performance was achieved by allowing evaluators to spend more time on product evaluations (rather than label approvals). The timeframe improvements were achieved at the same time that the APVMA received a 23.4 per cent increase in applications within the Pesticides Program and a 22.1 per cent increase in applications within the Veterinary Medicines Program compared to 2009-10.

Figure 4: Timeframe performance, 2009-11



Average elapsed time has also improved substantially from 2009–10 to 2010–11 as a result of the productivity improvements flowing from new labelling requirements. In 2009–10, a total of 1 199 pesticide product applications were finalised within timeframes. This represents 82 per cent of applications finalised within timeframe. In comparison, 1 498 pesticides applications were finalised within timeframes during 2010–11. This represents 86 per cent of applications finalised within timeframe. The number of decisions made by the APVMA increased by 23 per cent in 2010–11, despite an increase of 22 per cent in the number of applications received.

Table 21 and 22 provides information on the APVMA's results against its statutory timeframes.

**TABLE 21: PESTICIDE PROGRAM ELAPSED TIMES AND PER CENT FINALISED WITHIN TIMEFRAME 2009-10 AND 2010-11**

CLASS OF APPLICATION	2009-10		2010-11			
	TOTAL FINALISED	TOTAL FINALISED	FINALISED IN TIMEFRAME		TIME TO FINALISE (MONTHS)	
			NO.	%	AVERAGE CLOCK TIME	AVERAGE ELAPSED TIME
Received before 1 July 2005	16	7	1	14%	13–33	71–94
Modular	8	5	5	100%	0.1	18.4
2 to 3 months	1 114	1 430	1 327	93%	1.6	4.4
5 months	172	163	94	58%	6.2	14.8
6 to 8 months	83	71	34	48%	8.3	16.9
9 to 12 months	60	50	30	60%	10.0	23.4
13 to 15 months	11	13	7	54%	17.6	31.4
<b>TOTALS</b>	<b>1 464</b>	<b>1 739</b>	<b>1 498</b>	<b>86%</b>		

Source: APVMA Annual Reports 2009–10 and 2010–11

NOTE: Statistics do not include 261 applications received in screening that were either withdrawn by the applicant or treated as withdrawn in 2010–11. Although the APVMA did not accept these applications for evaluation, it regards them as finalised.

Applications have been classed based on the statutory timeframe allowed to complete the evaluation. The Average Clock Time is the time that the application is with the APVMA for evaluation. This excludes time that the APVMA spends waiting for further information required from the registrant. The Average Elapsed Time is the total time between the initial receipt of the application to the time of finalisation.

**TABLE 22: VETERINARY MEDICINES PROGRAM ELAPSED TIMES AND PER CENT FINALISED WITHIN TIMEFRAME 2009-10 AND 2010-11**

CLASS OF APPLICATION	2009-10		2010-11			
	TOTAL FINALISED	TOTAL FINALISED	FINALISED IN TIMEFRAME		TIME TO FINALISE (MONTHS)	
			NO.	%*	AVERAGE CLOCK TIME	AVERAGE ELAPSED TIME
Received before 1 July 2005	14	5	2	40%	1–19	70–91
Modular	1	2	2	100%	0.9	3.5
2 to 3 months	561	811	791	98%	0.9	5.1
5 months	160	171	146	85%	4.8	14.0
6 to 8 months	46	58	36	62%	9.5	24.0
9 to 12 months	22	24	15	63%	10.1	27.0
13 to 15 months	8	5	4	80%	13.4	30.3
<b>TOTALS</b>	<b>812</b>	<b>1 076</b>	<b>996</b>	<b>93%</b>		

*NOTE: Statistics do not include 129 applications received in screening that were either withdrawn by the applicant or treated as withdrawn in 2010–11. Although the APVMA did not accept these applications for evaluation, it regards them as finalised.*

### Further timeframe performance improvements as a result of the Better Regulation of Pesticides and Veterinary Medicines reforms

Current timeframes performance targets for product applications, active constituent applications and permit applications is shown in Table 23 below:

**TABLE 23: CURRENT TIMEFRAME PERFORMANCE TARGETS 2011-12 TO 2014-15**

DELIVERABLES	2011-12	2012-13	2013-14	2014-15
	BUDGET	FORWARD YEAR 1	FORWARD YEAR 2	FORWARD YEAR 3
Determine product applications within the statutory timeframe	88%	90%	90%	90%
Determine active constituent applications within the statutory timeframe	55%	60%	60%	60%
Determine permit applications within the statutory timeframe	85%	85%	85%	85%

Source: Department of Agriculture, Fisheries and Forestry, 2011-12, Portfolio Budget Statements (page 245)

Changes to the APVMA's business processes flowing from the Better Regulation of Agricultural and Veterinary Medicines reforms will enable the APVMA to further improve its timeframe performance. Efficiencies will develop as the APVMA implements new business processes. For example, efficiencies will result from a decreased administrative burden in managing poor applications, reduced technical input during preliminary assessment and a change to 'elapsed time' tracking of timeframes. Efficiencies will also result from the removal of some of the segmentation of the existing registration process allowing a

more streamlined process. A statutory timeframe will also be applied to the Chemical Review process. The effect of these efficiency improvements will take up to three years before they flow through to improvements in timeframe performance (particularly as some application categories stretch over 15 months).

The current statutory timeframes for applications made to the APVMA will be revised as part of the Better Regulation of Agricultural and Veterinary Medicines reforms. Currently these timeframes do not include the time taken for the applicant to respond to APVMA requirements. Consequently they reflect evaluation time rather than the time that elapses (elapsed time) between the date the application is accepted and the date on which the APVMA makes its decision on the application. The Better Regulation of Agricultural and Veterinary Medicines reforms provide greater certainty of when applications will be finalised by changing the statutory timeframes for applications to reflect a maximum allowable elapsed time. The change to an elapsed time system will result in changes to the existing statutory timeframes as well as the amount of time afforded applicants to respond to APVMA requirements.

The APVMA proposes to deliver further improvements in timeframe performance as a result of the implementation of the Better Regulation of Agricultural and Veterinary Medicines reforms as detailed in Table 24 below:

**TABLE 24: REVISED TIMEFRAME PERFORMANCE TARGETS 2011-12 TO 2014-15**

DELIVERABLES	2011-12	2012-13	2013-14	2014-15
	BUDGET	FORWARD YEAR 1	FORWARD YEAR 2	FORWARD YEAR 3
Determine product applications within the statutory timeframe	88%	90%	92%	95%
Determine active constituent applications within the statutory timeframe	55%	60%	65%	75%
Determine permit applications within the statutory timeframe	85%	85%	87%	92%

It is noteworthy that the timeframes shown above are delivered over a period of transition where the APVMA is effectively operating two discrete registration systems. Once the transition has been completed further improvements in timeframe performance will be possible.

### 3.12 Increasing compliance and enforcement

The APVMA currently lacks a modern, graduated compliance system. In particular, the compliance regime lacks mid-range enforcement measures, which hampers the APVMA's ability to apply a proportional response to non-compliance and to make full use of consideration of risk and extent of the non-compliance. The current agvet chemical framework also lacks any graduation between passive enforcement tools (warning letters and directions) and administrative or adversarial actions (suspension, cancellation, product recall and criminal prosecution).

The Better Regulation of Agricultural and Veterinary Medicines reforms introduce a range of new compliance enforcement tools that will result in the APVMA having a more contemporary and graduated compliance regime. The compliance 'toolkit' available to the APVMA will be substantially improved as a result of these changes. The changes to the compliance toolkit include the following:

- the ability to give an enforceable direction (to cease the non-compliant behaviour or to take remedial action)

- notices to produce or attend (to allow remote use of APVMA power)
- substantiation notices and the ability to make purchases of products for evidential purposes
- warnings and enforceable undertakings
- civil penalties
- penalty infringement notices (PINs)
- the ability for court ordered recovery of specific costs of investigation (e.g. chemical analysis)
- reforms to improve and streamline evidence collection, including for example providing for search warrants to be granted in jurisdictions other than the jurisdiction where the warrant is to be executed;
- providing for offences for non-compliance with conditions of a permit
- allowing for conditions to be applied to the import of unregistered or unapproved chemicals
- providing that existing provisions allowing suspension or cancellation of manufacturing licences be augmented by adding the imminent risk of unintended harm to animals as a reason for immediate action
- significant penalties for fraudulent information
- permits, approvals or registrations to be suspended or cancelled if the responsible person has been found to have provided fraudulent information
- provisions that allow for the efficient management of counterfeit active constituents and chemical products
- enhancing existing controls on active constituents and products to ensure their ongoing quality and integrity by providing for updateable statutory conditions of approval or registration.

Currently, the APVMA compliance sections do not have the resources to make best use of these new powers. To address this problem it is proposed to increase compliance and enforcement resources to allow for a full implementation of the new toolkit coupled with a strengthened compliance posture.

The intention is to increase audit and field activities with resulting graduated responses as required. The introduction of 'direction notices' and an infringement notice scheme will allow APVMA to respond to major instances of non-compliance with minimal impact on regular activities, through aligning regulatory effort to risk. A capacity for analysis would allow a more proactive response to emerging issues. Sampling and testing would also be undertaken to monitor marketplace compliance with statutory requirements.

The additional funding required will allow a total of five additional compliance staff to be recruited.

The increased resources would allow the full suite of compliance tools to be utilised while retaining the ability to respond to instances of major non-compliance.

### **3.13 Forecast operating results of proposed cost recovery arrangements**

Table 25 provides a summary of the forecast operating results for the next five years if the changes to the cost recovery arrangements in this Cost Recovery Discussion Paper are implemented.

TABLE 25: FORECAST OPERATING RESULTS 2011-12 TO 2014-15

	2011-12	2012-13	2013-14	2014-15
Income (\$)	34 703 181	30 361 817	31 081 589	33 005 639
Expense—Base (\$)	27 219 354	28 228 618	29 185 506	30 144 719
Add:				
Implementation of Reform Agenda <sup>11</sup>	3 453 553	2 750 000	1 668 154	-
Repayment of \$2 million to government	-	500 000	1 500 000	-
Increase compliance and enforcement activities	-	771 338	814 289	841 262
Continuation scheme (on-going operation)	-	574 555	1 230 734	1 949 764
Total expenses	30 672 907	32 824 511	34 398 683	32 935 745
Surplus/(deficit)	4 030 274	- 2 462 694	- 3 317 094	69 894
Financial Reserve (Equity)	11 462 165	8 999 471	5 682 377	5 752 271

### 3.14 Impact on companies of different sizes

The impact of the changes outlined in this Cost Recovery Discussion Paper on companies of different sizes is shown at Tables 43–45.

### 3.15 Implementation

It is proposed that the revised application fees, fees for continuation, new annual fees, a reduction in the levy and MLS licence fee changes would be given effect through changes to regulation and possibly by legal instrument.

Subject to the government's agreement to the revised cost recovery arrangements, which is anticipated to be in early 2012, at least two months' notification will be given of the date of effect of the changes. Application fee changes would apply to any new applications from 1 July 2012 or from the first collection period after the amendments to the regulations have commenced. Proposed implementation dates are shown in Table 26.

<sup>11</sup> The Reform Agenda has been funded by the \$8.75 million received from the Government. The majority of this funded was received in 2010-12 and 2011-12. Unspent reform funding inflates Equity over the period 2011-2013.

**TABLE 26: PROPOSED IMPLEMENTATION DATES BASED ON RELEASE OF FINAL CRIS BEFORE 30 JUNE 2012**

<b>REVISED ARRANGEMENTS</b>	<b>COMMENCEMENT</b>
Application fees to a minimum 30% cost recovery	From 1 July 2012
Application fees to a minimum 40% cost recovery	From 1 July 2013
2 tiered annual fee	From 1 July 2013
Other fees and charges	From 1 July 2012
Indexation on fees	From 1 July 2014
Levy rate change	For sales made from 1 July 2011

### 3.16 Summary of charging arrangements 2012-13

Table 27 provides a summary of the APVMA's proposed fees and charges for 2012–13.

TABLE 27: SCHEDULE OF FEES AND CHARGES 2012-13

ITEM OR ACTIVITY	PROPOSED METHOD OF RECOVERY	A		2012-13 COST RECOVERY PRICE VIA FEE (\$)	2012-13 COST RECOVERY PRICE VIA LEVY (\$)	B		=A x B FORECAST TOTAL COST (\$)
		ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE (\$)			FORECAST COST PER ITEM OR ACTIVITY <sup>12</sup> (\$)		
Category 1	Fee and levy	7	53 745	76 110	174 451	250 561	1 753 927	
Category 2	Fee and levy	14	The modular assessment fee <sup>13</sup>	The modular assessment fee	The remainder of the evaluation cost	The modular cost	Total modular cost	
Category 3	Fee and levy	3	34 925	49 095	112 301	161 396	484 188	
Category 4	Fee and levy	2	23 330	30 765	70 130	100 895	201 790	
Category 5	Fee and levy	41	3 630	4 085	9 400	13 485	552 885	
Category 6	Fee and levy	92	2 470	3 630	8 350	11 980	1 102 160	
Category 7	Fee and levy	367	660	1 450	3 328	4 778	1 753 526	
Category 8	Fee and levy	186	595	1 355	3 111	4 466	830 676	

<sup>12</sup> Cost per event or application

<sup>13</sup> The cost of an assessment under a modular categories (categories 2, 10, 14, 24 & 25) is the sum of the cost of each of the required modular items. Individual modular items are charged at 40% of their cost (30% in 2012-13), therefore the levy is required to recover the remaining cost of evaluation

**TABLE 27: SCHEDULE OF FEES AND CHARGES 2012-13**

ITEM OR ACTIVITY	PROPOSED METHOD OF RECOVERY	A		B		=A x B FORECAST TOTAL COST (\$)	
		ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE (\$)	2012-13 COST RECOVERY PRICE VIA FEE (\$)	2012-13 COST RECOVERY PRICE VIA LEVY (\$)		FORECAST COST PER ITEM OR ACTIVITY <sup>12</sup> (\$)
Category 9	Fee and levy	4	545	1 280	2 951	4 231	16 924
Category 10	Fee and levy	182	The modular assessment fee	The modular assessment fee	The remainder of the evaluation cost	The modular cost	Total modular cost
Category 11	Fee and levy	4	15 685	23 780	54 714	78 494	313 976
Category 12	Fee and levy	726	615	695	1 602	2 297	1 667 622
Category 13	Levy	171	Nil fee	900	2 070	2 970	507 870
Category 14	Fee and levy	688	The modular assessment fee	The modular assessment fee	The remainder of the evaluation cost	The modular cost	Total modular cost
Category 15	Fee	6	25 775	24 520	56 413	80 933	485 598
Category 16	Fee	1	4 430	14 660	33 734	48 394	48 394
Category 17	Fee	96	1 580	7 725	- 77	7 648	734 208
Category 18	Fee	15	1 005	1 835	4 214	6 049	90 735
Category 19	Fee and levy	31	350	350	2 369	2 719	84 289
Category 20	Fee and levy	287	350	350	2 369	2 719	780 353
Category 21	Fee and levy	134	350	350	2 369	2 719	418 726
Category 22	Levy	57	Nil fee	0	2 719	2 719	154 983

TABLE 27: SCHEDULE OF FEES AND CHARGES 2012-13

ITEM OR ACTIVITY	PROPOSED METHOD OF RECOVERY	A		2012-13 COST RECOVERY PRICE		B	=A x B
		ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE (\$)	RECOVERY PRICE VIA FEE (\$)	RECOVERY PRICE VIA LEVY (\$)	FORECAST COST PER ITEM OR ACTIVITY <sup>12</sup> (\$)	FORECAST TOTAL COST (\$)
Category 23	Fee and levy	135	The modular assessment fee	The modular assessment fee	The remainder of the evaluation cost	The modular cost	Total modular cost
Category 24	Fee and levy	4	The modular assessment fee	The modular assessment fee	The remainder of the evaluation cost	The modular cost	Total modular cost
Category 25	Fee and levy	7	The modular assessment fee	The modular assessment fee	The remainder of the evaluation cost	The modular cost	Total modular cost
Module 1	Fee and levy	1 018 <sup>14</sup>	505	590	707	1 297	1 320 346
Module 2.1	Fee and levy	7 <sup>15</sup>	3 255	6 915	15 906	22 821	159 747
Module 2.2	Fee and levy	7 <sup>15</sup>	2 230	2 355	5 412	7 767	54 369
Module 2.3	Fee and levy	103 <sup>15</sup>	1 030	1 185	2 728	3 913	403 039
Module 2.4	Fee and levy	182 <sup>15</sup>	200	575	1 318	1 893	344 526
Module 3.1	Fee and levy	2 <sup>15</sup>	19 490	24 730	56 896	81 626	163 252
Module 3.2	Fee and levy	3 <sup>15</sup>	14 620	13 305	30 605	43 910	131 730
Module 3.3	Fee and levy	42 <sup>15</sup>	2 900	3 445	7 926	11 371	477 582

<sup>14</sup> The volumes recorded against each of the modules represent the number completed when undergoing the assessment of the modular categories only

TABLE 27: SCHEDULE OF FEES AND CHARGES 2012-13

ITEM OR ACTIVITY	PROPOSED METHOD OF RECOVERY	A			B		=A x B
		ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE (\$)	2012-13 COST RECOVERY PRICE VIA FEE (\$)	2012-13 COST RECOVERY PRICE VIA LEVY (\$)	FORECAST COST PER ITEM OR ACTIVITY <sup>12</sup> (\$)	FORECAST TOTAL COST (\$)
Module 4	Fee and levy	8 <sup>15</sup>	3 720	2 155	4 963	7 118	56 944
Module 5.1	Fee and levy	2 <sup>15</sup>	5 595	14 105	32 455	46 560	93 120
Module 5.2	Fee and levy	13 <sup>15</sup>	4 765	8 165	18 792	26 957	350 441
Module 5.3	Fee and levy	2 <sup>15</sup>	2 490	6 275	14 441	20 716	41 432
Module 5.4	Fee and levy	20 <sup>15</sup>	2 230	5 720	13 158	18 878	377 560
Module 5.5	Fee and levy	1 <sup>15</sup>	1 175	1 525	3 502	5 027	5 027
Module 6.1	Fee and levy	2 <sup>15</sup>	4 310	3 555	8 177	11 732	23 464
Module 6.2	Fee and levy	27 <sup>15</sup>	2 900	2 535	5 839	8 374	226 098
Module 6.3	Fee and levy	6 <sup>15</sup>	1 435	2 600	5 974	8 574	51 444
Module 7.1	Fee and levy	2 <sup>15</sup>	12 605	17 050	39 231	56 281	112 562
Module 7.2	Fee and levy	8 <sup>15</sup>	3 255	5 680	13 061	18 741	149 928
Module 7.3	Fee and levy	8 <sup>15</sup>	620	1 070	2 462	3 532	28 256

TABLE 27: SCHEDULE OF FEES AND CHARGES 2012-13

ITEM OR ACTIVITY	PROPOSED METHOD OF RECOVERY	A		B		=A x B	
		ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE (\$)	2012-13 COST RECOVERY PRICE VIA FEE (\$)	2012-13 COST RECOVERY PRICE VIA LEVY (\$)	FORECAST COST PER ITEM OR ACTIVITY <sup>12</sup> (\$)	FORECAST TOTAL COST (\$)
Module 8.1	Fee and levy	25 <sup>15</sup>	1 865	1 865	4 290	6 155	153 875
Module 8.2	Fee and levy	96 <sup>15</sup>	750	770	1 765	2 535	243 360
Module 8.3	Fee and levy	82 <sup>15</sup>	500	455	1 050	1 505	123 410
Module 9	Fee and levy	- <sup>15</sup>	1 175	-	-	-	-
Module 10.1	Levy	- <sup>15</sup>	Nil fee	-	-	-	-
Module 10.2	Levy	2 <sup>15</sup>	Nil fee	-	-	-	-
Module 10.3	Levy	2 <sup>15</sup>	Nil fee	-	-	-	-
Module 11.1	Fee and levy	53 <sup>15</sup>	2 230	4 840	11 131	15 971	846 463
Module 11.2	Fee and levy	181 <sup>15</sup>	1 175	1 750	4 020	5 770	1 044 370
Module 11.3	Fee and levy	- <sup>15</sup>	620	655	1 511	2 166	-
Module 11.4	Fee and levy	674 <sup>15</sup>	160	790	1 823	2 613	1 761 162
Module 12	Fee and levy	265 <sup>15</sup>	170	305	694	999	264 735

<sup>15</sup> The volumes recorded against each of the modules represent the number completed when undergoing the assessment of the modular categories only.

<sup>15</sup> The volumes recorded against each of the modules represent the number completed when undergoing the assessment of the modular categories only.

TABLE 27: SCHEDULE OF FEES AND CHARGES 2012-13

ITEM OR ACTIVITY	PROPOSED METHOD OF RECOVERY	A		B		=A x B	
		ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE (\$)	2012-13 COST RECOVERY PRICE VIA FEE (\$)	2012-13 COST RECOVERY PRICE VIA LEVY (\$)	FORECAST COST PER ITEM OR ACTIVITY <sup>12</sup> (\$)	FORECAST TOTAL COST (\$)
Certificate of Export (no technical assessment)	Fee	295	125	160	-	162	47 790
Certificate of Export (requires technical assessment)	Fee	110	230	290	-	290	31 900
HGP Notification number application and renewal	Fee	361	305	295	-	296	106 856
Establishment of continuation scheme		N/a	N/a		574 555	574 555	574 555
Chemical Review and AERP	Annual fee and levy	N/a	N/a	1 812 371	755 792	2 568 163	2 568 163
Investigation and enforcement	Annual fee and levy	N/a	N/a	2 471 719	1 030 752	3 502 471	3 502 471
GMP	Fee and levy <sup>15</sup>	N/a.	MLS licence fee	120 000	1 381 704	1 501 704	1 501 704

<sup>15</sup> GMP recovery through the annual fee charged to eligible veterinary medicine products will be implemented in 2012–13. For the 2011–12 year, GMP will continue to be recovered by a combination of a MLS licence fee and the levy on wholesale sales of all agvet chemical products.

TABLE 27: SCHEDULE OF FEES AND CHARGES 2012-13

ITEM OR ACTIVITY	PROPOSED METHOD OF RECOVERY	A			B		=A x B
		ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE (\$)	2012-13 COST RECOVERY PRICE VIA FEE (\$)	2012-13 COST RECOVERY PRICE VIA LEVY (\$)	FORECAST COST PER ITEM OR ACTIVITY <sup>12</sup> (\$)	FORECAST TOTAL COST (\$)
Establishment of Reform Agenda reforms	Gov't Appropriation	N/a.	N/a.	2 750 000		2 750 000	2 750 000
<b>Total cost of activities</b>							<b>32 074 511</b>
Repayment of Reform Agenda funding	Levy	N/a.	N/a.			500 000	500 000
Deficit funded by equity	Equity						- 2 212 694
<b>Total fees and levies recovered</b>							<b>30 361 817</b>

### 3.17 Summary of fee and levy changes 2012-13 to 2015-16

Table 28 provides a summary of the projected changes to fees and levy rates. Fees in out years are based on estimated indexation rates. Where the actual indexation rate varies from the estimate, fees will increase or decrease accordingly.

**TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS**

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
APPLICATION FOR APPROVAL OF ACTIVE CONSTITUENT/S CONTAINED IN A PRODUCT, REGISTRATION OF THE PRODUCT AND APPROVAL OF THE PRODUCT LABEL/S						
Category 1	Application for approval of new active constituent/s contained in a product, registration of the associated product and approval of the product label requiring a full assessment of the active/s and product. <sup>18</sup>	15 months	53 745	76 110	104 640	108 105
Category 2	Application for approval of new active constituent/s contained in a product, registration of the associated product and approval of the product label other than as described in Category 1.	The modular assessment period	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee

<sup>16</sup> Legislative timeframes will change as a result of Reform Agenda. To calculate the assessment period for modular applications, add the longest assessment period for items 2–10 to the relevant item 11 assessment period.

<sup>17</sup> To calculate the fee for modular applications, total the modular fees for all items.

<sup>18</sup> A full assessment for this item is equivalent to the following Schedule 7 modules: 1, 2.1, 3.1, 4, 5.1, 6.1, 7.1, 8.1, 11.1 and 12.

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
APPLICATION FOR REGISTRATION OF A PRODUCT CONTAINING APPROVED ACTIVE CONSTITUENT/S AND APPROVAL OF THE PRODUCT LABEL						
Category 3	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) there is no registered product containing the active/s; and (b) a full assessment of the product is required. <sup>19</sup>	15 months	34 925	49 095	67 425	69 660
Category 4	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) there is a registered product containing the active/s; and (b) the product is to be used on a major food crop, where there are no relevant MRLs and drug or poison scheduling is required.	15 months	23 330	30 765	42 175	43 570
Category 5	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) the product is similar to a registered product; and (b) a full assessment of the product is required. <sup>20</sup>	5 months	3 630	4 085	5 630	5 815

<sup>19</sup> A full assessment for this item is equivalent to the following Schedule 7 modules: 1, 2.3, 3.3, 4, 5.1, 6.1, 7.1, 8.1, 11.1 and 12.

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
Category 6	<p>Application for registration of a product containing approved active constituent/s and approval of the product label if:</p> <ul style="list-style-type: none"> <li>(a) the product is closely similar to a registered product; and</li> <li>(b) efficacy and safety data is <b>not</b> required to demonstrate the similarity of the product to the registered product; and</li> <li>(c) chemistry and manufacture data is required.</li> </ul>	5 months	2 470	3 630	5 000	5 165
Category 7	<p>Application for registration of a chemical product containing approved active constituent/s and approval of the product label if:</p> <ul style="list-style-type: none"> <li>(a) the product is closely similar to a registered chemical product; and</li> <li>(b) efficacy and safety data is <b>not</b> required to demonstrate the similarity of the product to the registered product; and</li> <li>(c) chemistry and manufacture data is <b>not</b> required.</li> </ul>	3 months	660	1 450	1 995	2 060

<sup>20</sup> A full assessment for this item is equivalent to the following Schedule 7 modules: 1, 2.3, 3.3, 4, 5.1, 6.1, 7.1, 8.1, 11.1 and 12.

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
Category 8	Application for registration of a chemical product containing approved active constituent/s and approval of the product label if: (a) the product is the same as a registered chemical product; and (b) the product is to be registered with a different product name.	3 months	595	1 355	1 865	1 925
Category 9	Application for a listed registration of a chemical product containing approved active constituents and approval of the product label for which an established standard has been approved in accordance with s.56D of the Agvet Code.	3 months	545	1 280	1 765	1 825
Category 10	Application for registration of a chemical product containing approved active constituents (or an active for which the APVMA has received an application for approval) and approval of the product label for all situations other than as described in Categories 3–9.	The modular assessment period	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
APPLICATION TO VARY A REGISTRATION OR LABEL APPROVAL						
Category 11	Application to vary particulars or conditions of registration and/or label approval where the variation is to extend the use of the product to a major new food crop.	8 months	15 685	23 780	32 760	33 845

**TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS**

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
Category 12	Application to vary particulars or conditions of registration and/or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required.	3 months	615	695	960	990
Category 13	Application to vary particulars or conditions of registration or listed registration and/or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA.	3 months	Nil fee	Nil fee	Nil fee	Nil fee
Category 14	Application to vary particulars or conditions of registration or listed registration and/or label approval if the application is not of a kind described in Categories 11–13.	The modular assessment period	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
<b>APPLICATION FOR APPROVAL OF AN ACTIVE CONSTITUENT</b>						
Category 15	Application for approval of an active constituent requiring a full assessment.	12 months	25 775	24 520	33 775	34 895
Category 16	Application for approval of an active constituent requiring a toxicological assessment other than as described in Category 15.	8 months	4 430	14 660	20 195	20 865

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
Category 17	Application for approval of an active constituent other than as described in Categories 15 or 16.	5 months	1 580	7 725	7 980	8 245
APPLICATION FOR VARIATION TO AN APPROVED ACTIVE CONSTITUENT						
Category 18	Application to vary particulars or conditions of an approved active constituent.	5 months	1 005	1 835	2 525	2 610
APPLICATION FOR A PERMIT						
Category 19	Application for a permit to possess or supply, <b>other than for use in Australia</b> , an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product.	3 months	350	350	360	370
Category 20	Application for a permit where a previous assessment remains valid and no data of a technical nature is required.	3 months	350	350	360	370
Category 21	Application for a permit where the proposed use is a Minor Use. 21—assessment of 1 technical module 21a—assessment of >1 technical module	The modular assessment period	350	350	360	370
Category 22	Application for a permit in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an <b>emergency use</b> .	N/a	Nil fee	Nil fee	Nil fee	Nil fee

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
Category 23	Application for a permit in respect of a chemical product or an active constituent if the application is not of a kind referred to in Categories 19 to 21.	The modular assessment period	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
<b>OTHER APPLICATIONS</b>						
Category 24	Any other assessment of a technical nature for approval, registration or a permit not of a kind referred to in Categories 1–23, including assessment of a <b>protocol</b> designed to generate data to meet APVMA ‘Requirements and Guidelines’.	The modular assessment period	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 25	Any other application: (a) that is not made under section 10 of the Code; and (b) that is not of a kind listed in Categories 1–24; requiring assessment of a technical nature.	The modular assessment period		The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 26	Continuation fee	N/a	N/a	N/a	700	710
<b>MODULAR FEES</b>						
Module 1	Screening		505	590	610	630
Module 2.1	Chemistry—Level 1	12 months	3 255	6 915	9 525	9 840
Module 2.2	Chemistry—Level 2	8 months	2 230	2 355	3 240	3 350

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
Module 2.3	Chemistry—Level 3	5 months	1 030	1 185	1 635	1 685
Module 2.4	Chemistry—Level 4	3 months	200	575	790	815
Module 3.1	Toxicology—Level 1	12 months	19 490	24 730	34 065	35 195
Module 3.2	Toxicology—Level 2	8 months	14 620	13 305	18 325	18 935
Module 3.3	Toxicology—Level 3	4 months	2 900	3 445	4 745	4 900
Module 4	Toxicology— <i>Scheduling</i>	12 months	3 720	2 155	2 970	3 070
Module 5.1	Residues—Level 1	12 months	5 595	14 105	19 430	20 075
Module 5.2	Residues—Level 2 (Registration only)	6 months	4 765	8 165	11 250	11 625
Module 5.3	Residues—Level 3 (Permit only)	6 months	2 490	6 275	8 645	8 930
Module 5.4	Residues—Level 4 (Registration only)	3 months	2 230	5 720	7 880	8 140
Module 5.5	Residues—Level 5 (Permit only)	3 months	1 175	1 525	2 100	2 165
Module 6.1	OH&S—Level 1	12 months	4 310	3 555	4 895	5 060
Module 6.2	OH&S—Level 2	6 months	2 900	2 535	3 495	3 610
Module 6.3	OH&S—Level 3	4 months	1 435	2 600	3 580	3 695
Module 7.1	Environment—Level 1	12 months	12 605	17 050	23 490	24 265
Module 7.2	Environment—Level 2	6 months	3 255	5 680	7 820	8 080

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
Module 7.3	Environment—Level 3	4 months	620	1 070	1 475	1 525
Module 8.1	Efficacy and Safety—Level 1	5 months	1 865	1 865	2 570	2 655
Module 8.2	Efficacy and Safety—Level 2	4 months	750	770	1 060	1 095
Module 8.3	Efficacy and Safety—Level 3	3 months	500	455	630	650
Module 9	Non-food Trade	5 months	1 175	-	-	-
Module 10.1	Special Data—Level 1	12 months	Nil fee	Nil fee	Nil fee	Nil fee
Module 10.2	Special Data—Level 2	6 months	Nil fee	Nil fee	Nil fee	Nil fee
Module 10.3	<i>Any other assessment</i>	6 months	Nil fee	Nil fee	Nil fee	Nil fee
Module 11.1	Finalise—Type 1	3 months	2 230	4 840	6 665	6 885
Module 11.2	Finalise—Type 2 (Registration only)	2 months	1 175	1 750	2 410	2 490
Module 11.3	Finalise—Type 3 (Permit only)	2 months	620	655	905	935
Module 11.4	Finalise—Type 4	2 months	160	790	1 090	1 125
Module 12	Data Protection		170	305	415	430
Annual fee—	Agricultural and Non—GMP Veterinary products	n.a.	430	430	615	620
Annual fee—	GMP Veterinary products	n.a.	430	430	885	1 115

TABLE 28: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD <sup>16</sup>	CURRENT FEE (\$)	FEE ESTIMATE (\$) <sup>17</sup>		
				2012-13 (WCI/CPI 3.8%)	2013-14 (WCI/CPI 3.5%)	2014-15 (WCI/CPI 3.3%)
HGP application/ renewal fee		N/a.	295	295	305	315
Certificate of Export	No technical assessment	N/a	125	160	165	175
Certificate of Export	Requires technical assessment	N/a	230	290	300	310
Levy tier 1	\$0–\$1 000 000	N/a	0.80%	0.75%	0.57%	0.57%
Levy tier 2	\$1 000 001–\$5 000 000	N/a	0.45%	0.43%	0.30%	0.30%
Levy tier 3	More than \$5 000 001	N/a	0.30%	0.29%	0.15%	0.15%
Database information		N/a.	90/hr	95/hr	95/hr	100/hr
Advice		N/a	N/a	350	360	375
Advice (subsequent)		N/a	N/a	350	360	375

## 4 ONGOING MONITORING

### 4.1 Internal accountability structures

Internal accountability structures in the APVMA include the three-yearly Corporate Plan, the annual Operational Plan, the Risk Management Plan, the People Plan, the Fraud Control Plan, internal delegations, the quality control system and regular reviews of performance by the Chief Executive Officer (CEO) supported by the executive management team.

The APVMA's Audit Committee oversees an active Internal Audit Program. The Audit Committee reports to the CEO. An Advisory Board supports the CEO of the APVMA. The role of the Advisory Board is to provide advice and make recommendations to the CEO. The Advisory Board does not have decision-making power, but provides an expert consultative mechanism and informs the CEO. The CEO with the Executive Management team approves the budget and monitors the performance of the organisation.

Finally, the ISO Internal Audit Program also operates to assess the effectiveness of systems and the various risks arising from the APVMA's activities.

### 4.2 External accountability structures

The APVMA is subject to the same financial reporting requirements as other *Financial Management and Accountability Act 1997* agencies. Full accrual financial statements are produced for the APVMA's annual report each financial year. The Australian National Audit Office (ANAO) scrutinises the APVMA's accounts each year and the APVMA has, since its inception, always received unqualified audit reports from the ANAO. The APVMA is subject to the review of its budget and activities through the Senate Estimates process. Consultation also occurs through the APVMA's Industry Liaison Committee.

### 4.3 Monitoring mechanisms

The APVMA utilises an industry standard ABC model to support its cost recovery objectives. The financial model can then be used to test the effects of various business-operating options on the fee structure.

The APVMA endeavours to cost recover sufficient funds to ensure financial viability of sustainable operations. The APVMA therefore budgets to the point of minimal positive recovery (subject to the maintenance of the two-month operating cost [the financial reserve]) and the repayment of any specific funds in future years.

Following implementation of any revised cost recovery arrangements, the APVMA proposes to monitor the ongoing effectiveness of the cost recovery arrangements as set out in Table 29.

TABLE 29: ONGOING MONITORING MECHANISMS FOR THE REVISED COST RECOVERY ARRANGEMENTS

MECHANISM	HOW	PURPOSE
Stakeholder consultation	<p>Through the Industry Liaison Committee (ILC). The ILC is the main consultative forum between the APVMA and peak chemical organisations representing registrants. It meets three times per year</p> <p>Through the Registration Liaison Committee (RLC). The RLC is the main consultative forum between the APVMA, the states, territories and Commonwealth agencies relating to operational management of the NRS. It meets at least twice per year</p> <p>Through CEO meetings with major industry and community groups</p>	<p>Obtain feedback to allow the APVMA to adapt its approach to cost recovery in response to changing circumstances</p> <p>Reduce the impact of major reviews of cost recovery arrangements by allowing minor issues to be addressed as they arise</p> <p>Report on the alignment of costs and revenue (over and under recovery) for pre and post-market activities</p>
Cost recovery performance management arrangements	<p>Align the cost recovery arrangements with the operational plan and a performance improvement strategy. Industry will be consulted during this process</p> <p>Continue to utilise the annual report to demonstrate performance against the annual operational plan</p>	Enhance transparency of APVMA performance and reporting processes
Financial modelling	Test different cost scenarios and examine the net impact using ABC data and industry forecasts	Ensure fees and charges are aligned with product costs and the APVMA's financial strategy is achieved

#### 4.4 Periodic review

Whilst reviews of cost recovery arrangements are only required to be undertaken every five years the APVMA will complete another review of its cost recovery arrangements within the next three years (by 30 June 2015). This will allow sufficient time for business process changes flowing from the Better Regulation of Agricultural and Veterinary Medicines reforms to be fully implemented and flow through to applications which will then flow through to the ABC. It is noteworthy that applications can take a considerable time to work through the APVMA's business systems.

By 2015 sufficient quantities of applications will have been completed in sufficient numbers under the new processes to allow revised costs to be captured as part of an Activity Based Costing exercise. The data generated from this process can then be used to make adjustments to fees and charges. Any broader changes to the APVMA's functional responsibilities will trigger an earlier review and where a material amendment is made to these cost recovery arrangements a new CRIS will be prepared in accordance with the Guidelines.

A future CRIS in 2015 will also allow the government's decision flowing from the fundamental review of the APVMA's cost recovery arrangements to be adopted.

## 5 STAKEHOLDER CONSULTATION

The APVMA understands that predictability and sufficient notice is required where changes in fees and levies are to occur and undertook a stakeholder consultation program to inform, consult with and involve stakeholders in the development of revised cost recovery arrangements.

The APVMA is part of a complex environment of stakeholders and partners that interact to deliver a national management scheme and regulatory arrangements for agvet chemicals. The APVMA's stakeholders include the chemicals industry; the veterinary medicines industry; the general community; Australian, state and territory governments; farmers and farm workers; and other users of agvet chemicals.

Submissions from stakeholders on this Cost Recovery Discussion Paper are requested by 28 February 2012. Submissions should be sent to: [costrecovery@apvma.gov.au](mailto:costrecovery@apvma.gov.au)

### 5.1 Consultation objectives

This Cost Recovery Discussion Paper seeks to inform a CRIS to be completed in early 2012. The objectives of the consultation program are to:

- keep stakeholders fully informed of progress of the review
- provide stakeholders with opportunities for input
- consider and respond to stakeholder feedback.



## APPENDICES

## APPENDIX A: COST RECOVERY MODEL

Fee setting is not an exact science because it needs to take account of market price sensitivity and cost recovery policy as well as managing the operating result in accordance with the cost recovery policy and business strategy. Fee setting needs to be supported by financial modelling to determine the effects on the operating result and financial position in the out years. The APVMA has developed a robust and sophisticated cost recovery model that is based on a number of key assumptions and steps, including:

### Revenue

- forecast annual product sales
- target recovery for product registration costs
- proposed fee and levy changes for each fee item
- customer behaviour changes

### Expenditure

- calculation of fee item costs against revenue
- calculation of the average unit costs for each fee item compared with fees charged
- identification of expected changes to the cost structure (cost pressures such as labour and supplier costs, and resource levels)
- identification of the target level of capital expenditure

### Equity level

- capacity to fund provisions and working capital
- buffer to protect the APVMA against market volatility

The model enables fee setting over a five-year period (2012–13 to 2016–17). Figure 5 (see ‘Design of cost recovery model’ at page 73) shows a high-level design of the model.

## Cost allocations

The September 2011 ABC study identifies activity centres. It then assigns costs to services (cost drivers) on the basis of the number of events or transactions involved in the process of providing the APVMA’s services. The ABC study reports on the cost of registration activity by each application category and module. It also reports on the cost of other key APVMA activities. All overhead costs are included in the cost of the activities to ensure that these costs are also recovered, as outlined in the Guidelines.

## Method

The principal driver used in the ABC study is the percentage of staff time taken (by level) to perform each activity, which has been determined through staff effort surveys. Throughout the staff consultation phase, and later through the development of surveys, ten sections (Pesticides Registration, Pesticides Residues, Pesticides Chemistry, Chemical Review & AERP, Veterinary Registration, Veterinary Residues, Veterinary Chemistry, GMP, Application Management and Enquiries, and Compliance) allocated their time against different activities. The surveys were validated internally and follow-up sessions were held to ensure consistency. As different sections attribute their time differently (due to the nature of their work), the raw data captured through the survey process was then entered into an attribution model. Non-

service delivery activity costs (overheads) were aggregated and allocated to the nine sections in proportion to the staffing level in each section. It is common practice to allocate overheads in this manner. Overhead costs include:

- costs associated with the Executive, the Corporate Services Program (Quality Management System, Human Resources, Finance, Information Services, Information Technology, and Systems Design and Development), Public Affairs, Regulatory Reform and the Legal Program
- property costs
- depreciation
- insurance
- audit fees
- Advisory Board and committee costs
- postage and telephone.

All 'one-off' expenditure associated with the implementation of the Reform Agenda was excluded from the cost of activities. Capital costs were included in the cost of activities through depreciation only. The user cost of capital has not been separately identified, as the APVMA capital investment is low (about \$3 million), most of which is building fit-out.

Scientific assessment services are outsourced activities undertaken for the APVMA by the Office of Chemical Safety in the Department of Health and Ageing, and the Chemical Assessment Section in the Department of Sustainability, Environment, Water, Population and Communities. Some scientific assessment work (for example, work done under Chemical Review or the Ag QA Scheme) is not directly attributable to an individual registration category or module. This expenditure was incorporated into the total costs of the relevant section and then attributed in a manner consistent with the other costs of the section. An example calculation is shown in Table 30 below. Budget attributions are shown in Table 31.

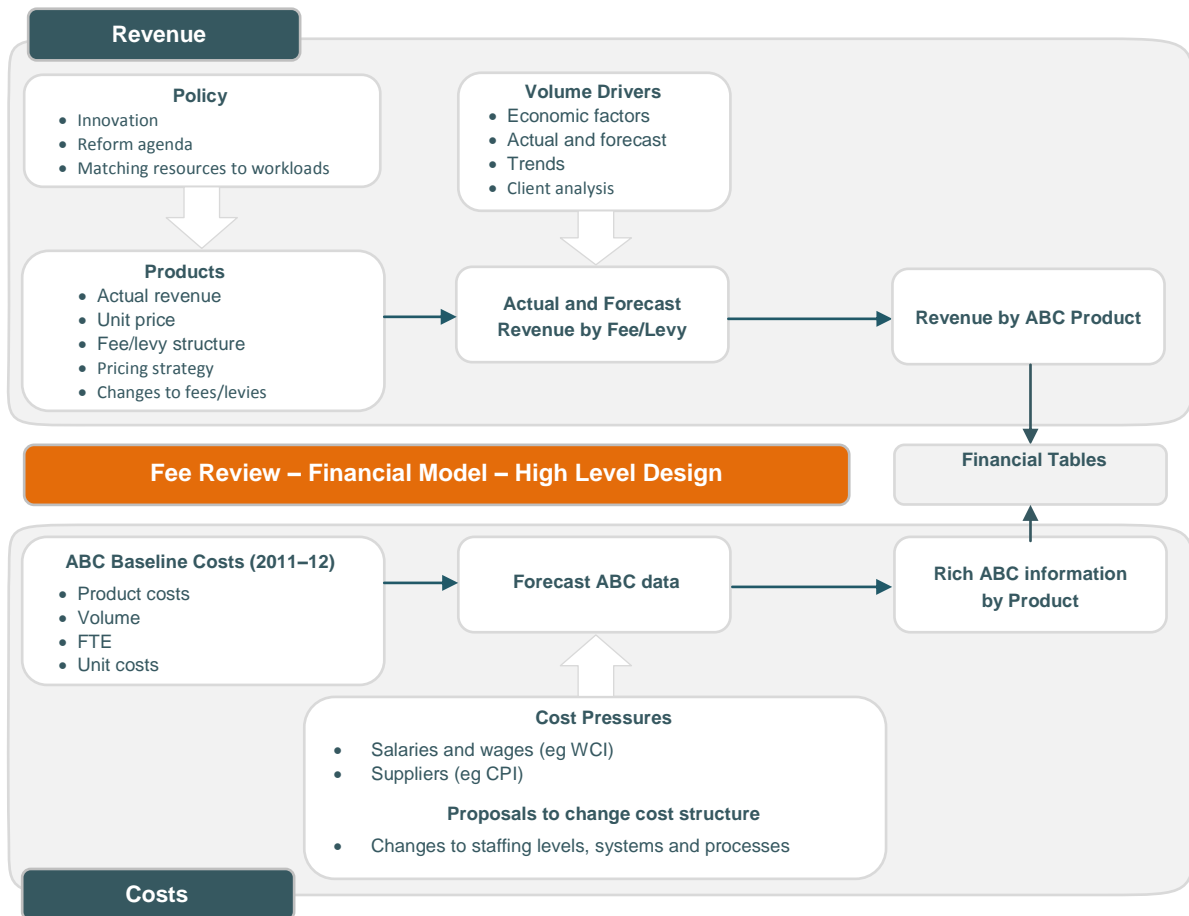
TABLE 30: DETAILED CALCULATION OF APPLICATION FEES PAYABLE ON 1 JULY 2012 AND 1 JULY 2013

CATEGORY	1	7	15
2010–11 assessment costs from ABC study			
Employee costs	\$39 104	\$2 132	\$13 342
External scientific assessments	\$150 031	–	\$46 993
Overheads	\$41 614	\$2 269	\$14 199
<b>TOTAL 2010-11 assessment costs</b>	<b>\$230 749</b>	<b>\$4 401</b>	<b>\$74 534</b>
Recovery rate	30%	30%	30%
<b>1 July 2012 application fee (adjusted for WPI/CPI)</b>	<b>\$76 110</b>	<b>\$1 450</b>	<b>\$24 520</b>
Recovery rate	40%	40%	40%
<b>1 July 2013 application fee (adjusted for WPI/CPI)</b>	<b>\$104 640</b>	<b>\$1 995</b>	<b>\$33 775</b>

TABLE 31: SUMMARY OF BUDGET ATTRIBUTION (2011-12)

SECTION	TOTAL ATTRIBUTION (\$)
REGISTRATION ACTIVITIES	
Pesticide application	5 075 164
Pesticide residues assessment	1 639 939
Pesticides chemistry assessment	1 700 095
Veterinary medicines application	2 929 272
Veterinary medicines residues assessment	815 011
Veterinary chemistry assessment	813 426
Applications management and enquiries	3 666 830
Scientific assessment services (direct to applications)	3 551 567
POST-REGISTRATION ACTIVITIES	
Adverse Experience Reporting Program (AERP) and Chemical Review	2 005 601
Compliance	2 782 075
GMP	1 459 245
Scientific assessment services (not relevant to applications)	781 129
REFORM ACTIVITIES	
Implementation of reforms	3 453 553
<b>Total</b>	<b>30 672 907</b>

Figure 5: Design of cost recovery model



## Cost recovery model assumptions

Baseline assumptions of the cost recovery model include:

- operating cost pressure is a weighted average of forecast WPI and CPI (75 per cent and 25 per cent respectively). The average indexation rate used in the model is 3.4 per cent a year based on recent year actuals
- enhanced regulatory compliance: additional \$0.8 million from 2012–13 to finance additional Compliance and Enforcement staff
- forecast annual product sales for each product type increasing at 2.4 per cent (apart from a drop of 4% in 2011-12 following the very strong sales recorded in 2010-11)
- forecast annual product registration applications: 0 per cent growth
- number of registered products: 2.5 per cent growth each year (apart from a drop of 2.5 per cent in veterinary GMP products in 2013–14)
- target recovery for product registration costs: at least 30 per cent from 1 July 2012 and 40 per cent from 1 July 2013
- repayment of \$2 million in 2012–13 and 2013–14.

The net impact is analysed in terms of the operating result and overall surplus position. The APVMA's financial strategy is to adjust expenditure on a timely basis in the event of a reduction in revenue due to a fall in applications or product sales below the planned level.

### Key changes to revenue streams

Table 32 below sets out the revenue composition planned at the time of the 2005 CRIS, the revenue composition highlighted by the 2011 ABC study, and the projected proportions for 2014–15.

TABLE 32: REVENUE COMPOSITION

REVENUE STREAM	2005 CRIS (2003-04)	ABC STUDY (2011-12)	2012 CRIS PROPOSED (2014-15)
Applications and other services (%)	22	16	31
Annual fee (%)	13	14	25
Levy revenue (%)	62	66	40
Parliamentary appropriations, including interest and interest equivalency payments (%)	3	3	3
Other revenue (%)	0	1	1
<b>Total (%)</b>	<b>100</b>	<b>100</b>	<b>100</b>

TABLE 33: COST OBJECT REVENUE ATTRIBUTION 2012-13 TO 2014-15

ACTIVITIES	EXPENSES (\$)	APPLICATION FEES & OTHER SERVICES (\$)	ANNUAL FEE (\$)	OTHER REVENUE (\$)	LEVY (\$)	TOTAL REVENUE (\$)
2012-13						
Registration activities	21 427 618	6 997 635			18 073 850	25 071 485
Post-registration activities	6 801 000		4 284 090	1 006 242		5 290 332
<b>Total (\$)</b>	<b>28 228 618</b>	<b>6 997 635</b>	<b>4 284 090</b>	<b>1 006 242</b>	<b>18 073 850</b>	<b>30 361 817</b>
<b>Total (%)</b>		<b>23%</b>	<b>14%</b>	<b>3%</b>	<b>60%</b>	<b>100%</b>

TABLE 33: COST OBJECT REVENUE ATTRIBUTION 2012-13 TO 2014-15

ACTIVITIES	EXPENSES (\$)	APPLICATION FEES & OTHER SERVICES (\$)	ANNUAL FEE (\$)	OTHER REVENUE (\$)	LEVY (\$)	TOTAL REVENUE (\$)
2013-14						
Registration activities	23 389 957	9 649 100			13 323 467	22 972 567
Post-registration activities	7 026 283		7 082 610	1 026 412		8 109 022
<b>Total (\$)</b>	<b>30 416 240</b>	<b>9 649 100</b>	<b>7 082 610</b>	<b>1 026 412</b>	<b>13 323 467</b>	<b>31 081 589</b>
<b>Total (%)</b>		<b>31%</b>	<b>23%</b>	<b>3%</b>	<b>43%</b>	<b>100%</b>
2014-15						
Registration activities	24 835 453	10 312 735			13 584 543	23 897 278
Post-registration activities	7 259 030		8 086 685	1 021 676		9 108 361
<b>Total (\$)</b>	<b>32 094 483</b>	<b>10 312 735</b>	<b>8 086 685</b>	<b>1 021 676</b>	<b>13 584 543</b>	<b>33 005 639</b>
<b>Total (%)</b>		<b>31%</b>	<b>25%</b>	<b>3%</b>	<b>41%</b>	<b>100%</b>

## Operating result

Table 34 outlines the overall results of the proposed cost recovery scenario. This scenario achieves the APVMA's financial plan to maintain equity at around two months operating costs.

TABLE 34: FINANCIAL RESULT

	2012-13	2013-14	2014-15
Income (\$ million)	30 361 817	31 081 589	33 005 639
Expense (\$ million)	32 824 511	34 398 683	32 935 745
Surplus/(deficit) (\$ million)	- 2 462 694	- 3 317 094	69 894
Retained surplus/(deficit) (\$ million)	8 999 471	5 682 377	5 752 271

## Upfront cost recovery rate

The proposed scenario achieves the APVMA's 40 per cent upfront cost recovery strategy, as Table 35 illustrates. Since some fees are 100 per cent cost-recovered, the net 'initial fees cost recovery' rate is slightly higher than 40 per cent.

TABLE 35: UPFRONT COST RECOVERY

	2012-13	2013-14	2014-15	2015-16
Revenue (applications and other services) (\$)	6 997 635	9 649 100	10 312 735	10 789 430
Expenses (applications and other services) (\$)	21 427 618	23 389 957	24 835 453	25 550 870
Initial fees cost recovery (%)	33%	41%	42%	42%

## Levy rates

The proposed scenario results in a reduced reliance on the levy. The revised rates are outlined in Table 36 below. The existing cost recovery arrangements recover the cost of all post market activities (Chemical Review, AERP and Compliance) through the levy. Under the proposed arrangements these costs will be funded through the Annual Fee(s). This, together with the restoration of the 40 per cent target for up front component of application fees allows the reduction in levy rates shown below.

TABLE 36: LEVY RATES

	2012-13	2013-14	2014-15
<i>(based on sales during</i>	<i>2011-12</i>	<i>2012-13</i>	<i>2013-14</i>
Levy tier 1 (%)	0.75%	0.57%	0.57%
Levy tier 2 (%)	0.43%	0.30%	0.30%
Levy tier 3 (%)	0.29%	0.15%	0.15%

Tiered levy thresholds are based on:

- no levy is collected for annual product sales up to \$5 000 (as it is not efficient to do so)
- levy tier 1 rate for annual product sales up to \$1 000 000
- levy tier 2 rate for annual product sales from \$1 000 001 to \$5 000 000
- levy tier 3 rate for annual product sales above \$5 000 000.

Note that the increase in application fees has enabled the levy rates to be reduced.

As the levy remains the balancing factor, unexpected falls in other revenue sources or additional demands from stakeholders that require staff or supplier resources may lead to further revisions of the levy rates proposed in Table 36. In accordance with the Guidelines, a material change to the levy would trigger a new CRIS to be prepared.

## APPENDIX B: SECTION CONTRIBUTION TO THE COST OF APPLICATIONS FOR REGISTRATION AND APPROVAL

TABLE 37: SECTION CONTRIBUTION TO THE COST OF APPLICATION CATEGORIES

SECTION	COST (\$) OF CATEGORIES (2012-13) <sup>21</sup>								
	1 <sup>22</sup>	3	4	5	6	7	8	9	11
Pesticide & Veterinary Registrations	15 306	15 306	15 306	5 912	5 912	2 534	2 354	2 219	15 306
Pesticide & Veterinary Residues	42 879	42 879	24 825	-	-	296	296	296	24 825
Pesticide & Veterinary Chemistry	21 016	3 603	3 603	3 603	3 603	-	-	-	-
AME	1 517	1 517	1 517	1 517	1 517	1 571	1 463	1 381	1 517
SAS	150 031	85 330	47 666	1 386	-	-	-	-	30 640
<b>Total<sup>23</sup></b>	<b>230 749</b>	<b>148 635</b>	<b>92 917</b>	<b>12 418</b>	<b>11 032</b>	<b>4 401</b>	<b>4 113</b>	<b>3 896</b>	<b>72 288</b>

TABLE 38: SECTION CONTRIBUTION TO THE COST OF APPLICATION CATEGORIES (CONTINUED)

SECTION	COST (\$) OF CATEGORIES (2012-13) <sup>24</sup>									
	12	13	15	16	17	18	19	20	21	22
Pesticide & Veterinary Registrations	1 639	2 259	920	920	920	-	1 342	1 342	1 342	1 342
Pesticide & Veterinary Residues	-	-	-	-	-	-	-	-	-	-
Pesticide & Veterinary Chemistry	-	-	26 621	26 621	6 123	5 571	-	-	-	-
AME	476	476	-	-	-	-	1 162	1 162	1 162	1 162
SAS	-	-	46 993	17 026	-	-	-	-	-	-
<b>Total<sup>51</sup></b>	<b>2 115</b>	<b>2 735</b>	<b>74 534</b>	<b>44 567</b>	<b>7 043</b>	<b>5 571</b>	<b>2 504</b>	<b>2 504</b>	<b>2 504</b>	<b>2 504</b>

<sup>21</sup> Categories 2, 10 & 14 do not appear as they are modular categories.

<sup>22</sup> Categories 1,3 and 4 costs are the sum of the relevant fixed module costs

<sup>23</sup> Total cost for category, where relevant, takes average cost of Pesticides Residues and Veterinary Residues and average cost of Pesticides Registration and Veterinary Registration.

<sup>24</sup> Categories 14 and 23–25 do not appear as they are modular categories.

TABLE 39: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST (\$) OF MODULES (2012-13)								
	1	2.1	2.2	2.3	2.4	3.1	3.2	3.3	4
Pesticide & Veterinary Registrations	718	-	-	-	-	-	-	-	-
Pesticide & Veterinary Residues	-	-	-	-	-	-	-	-	-
Pesticide & Veterinary Chemistry	-	21 016	7 152	3 603	1 743	-	-	-	-
AME	476	-	-	-	-	-	-	-	-
SAS	-	-	-	-	-	75 172	10 471	10 471	6 555
<b>Total<sup>25</sup></b>	<b>1 194</b>	<b>21 016</b>	<b>7 152</b>	<b>3 603</b>	<b>1 743</b>	<b>75 172</b>	<b>10 471</b>	<b>10 471</b>	<b>6 555</b>

TABLE 40: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST (\$) OF MODULES (2007-08)								
	5.1	5.2	5.3	5.4	5.5	6.1	6.2	6.3	
Pesticide & Veterinary Registrations	-	-	-	-	-	-	-	-	-
Pesticide & Veterinary Residues	42 879	24 825	19 078	17 385	4 629	-	-	-	
Pesticide & Veterinary Chemistry	-	-	-	-	-	-	-	-	
AME	-	-	-	-	-	-	-	-	
SAS	-	-	-	-	-	10 805	7 712	7 896	
<b>Total<sup>53</sup></b>	<b>42 879</b>	<b>24 825</b>	<b>19 078</b>	<b>17 385</b>	<b>4 629</b>	<b>10 805</b>	<b>7 712</b>	<b>7 896</b>	

<sup>25</sup> Total cost of module, where relevant, takes average cost of Pesticides Residues and Veterinary Residues and average cost of Pesticides Registration and Veterinary Registration.

TABLE 41: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST (\$) OF MODULES (2007-08)						
	7.1	7.2	7.3	8.1	8.2	8.3	9
Pesticide & Veterinary Registrations	-	-	-	-	-	-	-
Pesticide & Veterinary Residues	-	-	-	-	-	-	-
Chemistry	-	-	-	-	-	-	-
AME	-	-	-	-	-	-	-
SAS	51 831	17 259	3 253	5 668	2 335	1 386	-
<b>Total<sup>26</sup></b>	<b>51 831</b>	<b>17 259</b>	<b>3 253</b>	<b>5 668</b>	<b>2 335</b>	<b>1 386</b>	<b>-</b>

TABLE 42: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST (\$) OF MODULES (2007-08)							
	10.1	10.2	10.3	11.1	11.2	11.3	11.4	12
Pesticide & Veterinary Registrations	-	-	-	13 667	4 273	1 150	1 501	920
Pesticide & Veterinary Residues	-	-	-	-	-	-	-	-
Chemistry	-	-	-	-	-	-	-	-
AME	-	-	-	1 041	1 041	845	905	-
SAS	-	-	-	-	-	-	-	-
<b>Total<sup>54</sup></b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>14 708</b>	<b>5 314</b>	<b>1 995</b>	<b>2 406</b>	<b>920</b>

<sup>26</sup> Total cost of module, where relevant, takes average cost of Pesticides Residues and Veterinary Residues and average cost of Pesticides Registration and Veterinary Registration.

## APPENDIX C: IMPACT OF CHANGES OF COMPANIES OF DIFFERENT SIZES

TABLE 43: COMPARISON OF FEES PAID BY A TYPICAL LARGE COMPANY FROM 2011-12 TO 2014-15

	2011-12	2012-13	2013-14	2014-15
<b>LEVY:</b>				
70 Products with sales of \$300 000 each	168 000	157 500	119 700	119 700
34 Products with sales of \$2 000 000 each	425 000	401 200	295 800	295 800
3 Products with sales of \$6 000 000 each	87 000	82 800	57 600	57 600
<b>Total levies paid</b>	<b>680 000</b>	<b>641 500</b>	<b>473 100</b>	<b>473 100</b>
<b>ANNUAL FEE:</b>				
70 Ag & Vet non GMP products renewed	30 100	30 100	43 050	43 400
37 Vet GMP products renewed	15 910	15 910	32 745	41 255
<b>Total annual fees paid</b>	<b>46 010</b>	<b>46 010</b>	<b>75 795</b>	<b>84 655</b>
<b>APPLICATION FEES:</b>				
1 Category 4 application lodged	23 330	30 765	42 175	43 570
4 Category 7 applications lodged	2 640	5 800	7 980	8 240
5 Category 8 applications lodged	2 975	6 775	9 325	9 625
21 Category 12 applications lodged	12 915	14 595	20 160	20 790
<b>Total application fees paid</b>	<b>41 860</b>	<b>57 935</b>	<b>79 640</b>	<b>82 225</b>
<b>CONTINUATION FEES:</b>				
10 products requiring continuation	N/a	N/a	7 000	7 100
<b>Overall fees and levies paid</b>	<b>767 870</b>	<b>745 445</b>	<b>635 535</b>	<b>647 080</b>

This table demonstrates that large companies will pay lower fees to the APVMA, based on a static number of products and consistent sales revenue. A slight increase occurs in 2014-15 due the effects on indexation on application and annual fees.

TABLE 44: COMPARISON OF FEES PAID BY A TYPICAL MEDIUM COMPANY FROM 2011-12 TO 2014-15

	2011-12	2012-13	2013-14	2014-15
<b>LEVY:</b>				
41 Products with sales of \$250 000 each	82 000	76 875	58 425	58 425
7 Products with sales of \$2 000 000 each	87 500	82 600	60 900	60 900
<b>Total levies paid</b>	<b>169 500</b>	<b>159 475</b>	<b>119 325</b>	<b>119 325</b>
<b>ANNUAL FEE:</b>				
31 Ag & Vet non GMP products renewed	13 330	13 330	19 065	19 220
17 Vet GMP products renewed	7 310	7 310	15 045	18 955
<b>Total annual fees paid</b>	<b>20 640</b>	<b>20 640</b>	<b>34 110</b>	<b>38 175</b>
<b>APPLICATION FEES:</b>				
2 Category 7 applications lodged	1 320	2 900	3 990	4 120
2 Category 8 applications lodged	1 190	2 710	3 730	3 850
8 Category 12 applications lodged	4 920	5 560	7 680	7 920
<b>Total application fees paid</b>	<b>7 430</b>	<b>11 170</b>	<b>15 400</b>	<b>15 890</b>
<b>CONTINUATION FEES:</b>				
5 products requiring continuation	N/a	N/a	3 500	3 550
<b>Overall fees and levies paid</b>	<b>197 570</b>	<b>191 285</b>	<b>168 835</b>	<b>173 390</b>

This table demonstrates that medium companies will pay lower fees to the APVMA, based on a static number of products and consistent sales revenue.

TABLE 45: COMPARISON OF FEES PAID BY A TYPICAL SMALL COMPANY FROM 2011-12 TO 2014-15

	2011-12	2012-13	2013-14	2014-15
<b>LEVY:</b>				
7 Products with sales of \$175 000 each	9 800	9 188	6 983	6 983
<b>Total levies paid</b>	<b>9 800</b>	<b>9 188</b>	<b>6 983</b>	<b>6 983</b>
<b>ANNUAL FEE:</b>				
5 Ag & Vet non GMP products renewed	2 150	2 150	3 075	3 100
2 Vet GMP products renewed	860	860	1 770	2 230
<b>Total annual fees paid</b>	<b>3 010</b>	<b>3 010</b>	<b>4 845</b>	<b>5 330</b>
<b>APPLICATION FEES:</b>				
1 Category 7 applications lodged	660	1 450	1 995	2 060
2 Category 12 applications lodged	1 230	1 390	1 920	1 980
<b>Total annual fees paid</b>	<b>1 890</b>	<b>2 840</b>	<b>3 915</b>	<b>4 040</b>
<b>CONTINUATION FEES:</b>				
5 products requiring continuation	N/a	N/a	700	710
<b>Overall fees and levies paid</b>	<b>14 700</b>	<b>15 038</b>	<b>15 743</b>	<b>16 353</b>

This table demonstrates that for a small company indicates that there will be a small increase in fees payable to the APVMA as a result of the proposed fee structure, based on a static number of products and consistent sales revenue.

## GLOSSARY OF TERMS AND ABBREVIATIONS

ABC	The APVMA's 2011 Activity Based Costing model used to establish the cost of current activities
AERP	Adverse Experience Reporting Program
Ag QA Scheme	Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products
Ag	Agricultural
Agvet chemicals	Agricultural and veterinary chemicals
Agvet Code	The Agricultural and Veterinary Chemicals Code which is a Schedule to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
Basic product set	Products and services that the Government agrees should be funded by taxpayers
CAC Act	<i>Commonwealth Authorities and Companies Act 1997</i>
CEO	Chief Executive Officer
Commercial benefit	The APVMA considers activities undertaken by departments/agencies either through contract research or in-house, and where those activities produce intellectual property, which may later be sold for profit, or are conducted on a fee-for-service basis as commercial benefit. Additionally other activities not considered to be fee exempt would include activities where a profit is attracted from investment and/or the service provided (for example commercial forestry operations and water storages).
Core business	The APVMA considers 'core business' to be activities that are undertaken by officers of the government agency that are directly related to a control strategy being developed, implemented and communicated by that government agency. This includes activities relating to noxious or declared weed control programs, the management of exotic pests and diseases or market access issues associated with produce under existing Interstate Certification Assurance (ICA) requirements. Such activities would be fee exempt. Activities that relate to servicing grower needs via extension or industry development officers employed by government agencies are not considered as core business for the purposes of seeking approvals for permits and requesting subsequent fee exemptions on behalf of industries that would otherwise pay a fee. Additionally, whilst some government departments and their officers engage in activities relating to how to manage pests and diseases, the actual management of those pests and diseases by those government agencies is not core business of those agencies. In these circumstances government officers operating on behalf of primary industry groups may lodge applications, however the appropriate fee would apply and no exemptions would be granted.
Cost recovery	Fees and charges related to the provision of government goods and services (including regulation) to the private and other non-government sectors of the economy
Cost recovery charge	The mode by which the APVMA recovers the costs of some of the services they provide. Australian Government cost recovery charges fall into two broad categories: <ul style="list-style-type: none"><li>• fees for goods and services</li><li>• 'cost recovery' taxes (primarily levies, but also some excises and customs duties).</li></ul>

Cost recovery policy framework	Cost recovery principles endorsed by the Primary Industries Standing Committee (PISC) in July 2002.
CPI	Consumer Price Index. The CPI measures changes over time in the prices of a wide range of consumer goods and services acquired by Australian metropolitan households and it is published quarterly, three to four weeks after the end of the reference quarter <sup>27</sup> .
CRIS	Cost Recovery Impact Statement. A statement documenting compliance with the cost recovery policy. Only those agencies with significant cost recovery arrangements must prepare a CRIS.
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
EU	European Union
FMA Act	<i>Financial Management and Accountability Act 1997</i>
FMA Act agencies	Agencies that are financially part of the legal entity of the Commonwealth and are subject to the FMA Act
GMP	Good Manufacturing Practice
Guidelines	Australian Government Cost Recovery Guidelines (July 2005)
HGP	Hormonal Growth Promotant
HGP Scheme	Hormonal Growth Promotant Scheme. The HGP Scheme involves the authorisation and auditing of importers and suppliers of HGPs, as required by the Agvet Code, in collaboration with state departments.
ILC	Industry Liaison Committee
Indexation rate	The indexation rate is comprised from 75% of the WPI and 25% of the CPI
Information activities	Activities involved in collecting, compiling and disseminating information or any other activity of a non-regulatory nature
MLS	Manufacturers' Licensing Scheme
NCPR	National Competition Policy Review 1999
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals. The NRS sets out the regulatory arrangements for the management of agvet chemicals in Australia. The APVMA administers the scheme's legislation in partnership with state and territory governments and with the active involvement of other Australian government agencies.
OECD	Organization for Economic Co-operation and Development
PISC	Primary Industries Standing Committee
Reform Agenda	Better Regulation of Agricultural and Veterinary Chemicals
Regulatory activities	Activities involved in administering regulations

.....  
<sup>27</sup> Australian Bureau of Statistics, 2007, Consumer Price Index, viewed 26 September 2011, <<http://www.abs.gov.au/AUSSTATS/abs@.nsf/DSSbyCollectionid/1E564CACF4CBEC32CA256ED8007EF06E?opendocument>>

RLC	Regulatory Liaison Committee
SAS	Scientific Assessment Services
SWG	Signatories Working Group. A committee composed of representatives of Australian, state and territory governments, established by the Australian Government during the previous cost recovery review to establish the most appropriate and cost effective cost recovery model
Stopped products	Registered products that have not had their registration renewed. Once unregistered, they can no longer be manufactured. However, the product can be sold for another two years (shelf life of two years), unless the APVMA deems otherwise.
Vet	Veterinary
WIP	Work in Progress
WPI	Wage Price Index. The WPI broadly measures changes in the wages paid by Australian businesses to employees and it is compiled and published quarterly, about 6 to 7 weeks after the end of the reference quarter <sup>28</sup> .

---

<sup>28</sup> Australian Bureau of Statistics, 2004, Labour Price Index: Concepts, Sources and Methods, 6351.0.55.001, viewed 14 January 2009, <<http://www.abs.gov.au/ausstats/abs@.nsf/66f306f503e529a5ca25697e0017661f/973c7a0104155de0ca256fb0007bcd1!OpenDocument>>