Australian Government

Australian Pesticides and Veterinary Medicines Authority

COST RECOVERY IMPACT STATEMENT

Covering the period 1 July 2013 – 30 June 2015

ISBN 978-1-922188-09-0 (electronic)

Ownership of intellectual property rights in this publication

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Creative Commons licence

With the exception of the Coat of Arms and other elements specifically identified, this publication is licensed under a Creative Commons Attribution 3.0 Australia Licence. This is a standard form agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work.

A summary of the licence terms is available from www.creativecommons.org/licenses/by/3.0/au/deed.en. The full licence terms are available from www.creativecommons.org/licenses/by/3.0/au/legalcode.

The APVMA's preference is that you attribute this publication (and any approved material sourced from it) using the following wording:

> *Source: Licensed from the Australian Pesticides and Veterinary Medicines Authority (APVMA) under a Creative Commons Attribution 3.0 Australia Licence.*

In referencing this document the Australian Pesticides and Veterinary Medicines Authority should be cited as the author, publisher and copyright owner.

Use of the Coat of Arms

The terms under which the Coat of Arms can be used are set out on the Department of the Prime Minister and Cabinet website (see www.dpmc.gov.au/guidelines).

Disclaimer

The material in or linking from this report contains the views or recommendations of third parties. This material does not necessarily reflect the views of the APVMA, or indicate a commitment to a particular course of action.

There may be links in this document that will transfer you to external websites. The APVMA does not have responsibility for these websites, nor does linking to or from this document constitute any form of endorsement.

The APVMA is not responsible for any errors, omissions or matters of interpretation in any third-party information contained within this document.

Comments and enquiries about copyright:

The Director, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@apvma.gov.au

This publication is available from the APVMA website: www.apvma.gov.au.

Errata

This version of the APVMA's Cost Recovery Impact Statement (2013–15) was published 4 December 2012. The original version published on 29 November 2012 contained two errors. The missing verso page has been inserted in this version. A typographical error was present in table 8, with the annual cost of the overheads item incorrectly recorded as $1 099 703. The correct value of $1 009 703 now appears on page 21.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

1 INTRODUCTION

1.1 Purpose

The purpose of this Cost Recovery Impact Statement (CRIS) is to document the cost recovery activities of the Australian Pesticides and Veterinary Medicines Authority (APVMA) and to demonstrate their consistency with the *Australian Government Cost Recovery Guidelines* (July 2005)[1] (the Guidelines).

Key changes to the APVMA's cost recovery activities reflected in this CRIS include:

- returning application fees to 40 per cent cost recovery level
- recovering close to 100 per cent of the costs associated with compliance with Good Manufacturing Practice (GMP)
- implementing a number of new fees and charges for activities flowing from the implementation of the Better Regulation of Agricultural and Veterinary Chemicals reforms.

1.2 Duration

This CRIS covers the period 1 July 2013 – 30 June 2015 (2 years). During this period a First-principles Review of the APVMA's cost recovery arrangements will be completed.

The introduction of some new fees and charges outlined in this CRIS are subject to the passage of the Better Regulation of Agricultural and Veterinary Chemicals reform legislation and associated regulations.

1.3 About the APVMA

The APVMA is the independent Australian Government statutory authority responsible for the assessment and registration of agricultural chemicals and veterinary medicines (agvet chemicals) and for their regulation up to and including the point of retail sale. The states and territories are responsible for regulating and managing the use of agvet chemicals once they are sold. The regulatory framework for managing agvet chemicals in Australia is collectively referred to as the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The APVMA assesses applications from companies and individuals seeking registration so they can supply their product to the marketplace. Applications undergo rigorous assessment using the expertise of the APVMA's scientific staff and drawing on the technical knowledge of other relevant scientific organisations, Commonwealth government departments and state agriculture departments. If the scientific data confirms that when the product is used as directed on the product label it would not be an undue hazard to the safety of people or have unintended effects on people, animals, the environment or international trade, then the APVMA will register the product.

The APVMA also undertakes quality assurance and compliance functions.

1.4 Australian Government cost recovery policy

In December 2005, 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

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

allocation of resources. The cost recovery policy is administered by the Department of Finance and Deregulation and outlined in the Guidelines and *Finance Circulars* 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 section 48A or former sections 28 or 43 of the CAC Act. 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 policy.

1.5 Interim cost recovery arrangements

In early 2011 the government announced its intention to proceed with the Better Regulation of Agricultural Chemicals and Veterinary Medicines reforms (see www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals). The reforms introduce a number of new activities, and the fees and charges for these are reflected in this CRIS. In mid-2011 independent consultants undertook an Activity Based Costing (ABC) study which provided an analysis of the costs associated with the APVMA's various activities.

A Cost Recovery Discussion Paper which included the data generated by the ABC study was released in December 2011. A further Supplementary Discussion Paper proposing alternate arrangements for the cost recovery of compliance with Good Manufacturing Practice (GMP) was released in May 2012. See www.apvma.gov.au/consultation/public/2012/cost_recovery_gmp.php

Both discussion papers invited interested parties to provide written submissions. The submissions, together with the APVMA's responses, are available at www.apvma.gov.au/about/work/cost_recovery.php.

A summary of the submissions received and the APVMA's response is shown at Section 5.1.

In August 2012 the government announced that a First-principles Review of the APVMA's cost recovery framework was being undertaken (see discussion below). In view of the First-principles review timeframe, this CRIS covers the period from 1 July 2013 to 30 June 2015.

1.6 First-principles Review of cost recovery

As noted above a First-principles Review of the APVMA's cost recovery arrangements commenced in August 2012. This review is being undertaken by the Department of Agriculture, Fisheries and Forestry (DAFF) in consultation with the APVMA and the Department of Finance and Deregulation and will result in a submission to the Australian Government. It is anticipated the review will be completed over a 2-year period, and after the conclusion of the review of the Guidelines being conducted by the Department of Finance and Deregulation (DoFD).

Subject to Government's decision on recommendations from the First-principles Review, a new CRIS reflecting any revised cost recovery arrangements will be developed by the APVMA. New arrangements are expected to commence from 1 July 2015, depending on the passage of any legislative amendments.

The First-principles Review will cover all aspects of the APVMA's cost recovery arrangements. Separate and detailed consultation with stakeholders will occur as part of this process.

Further information on the review is available on the DAFF website at: www.daff.gov.au/agriculture-food/ag-vet-chemicals/first-principles-review-of-the-apvmas-cost-recovery-arrangements.

1.7 Legal basis for the imposition of fees and 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 Hormonal Growth Promotants (HGP) notification numbers and their renewal) are provided for in the *Agricultural and Veterinary Chemicals Code Regulations 1995* made under the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act). Fees for the Manufacturers' Licensing Scheme (MLS) are also provided for in the Agvet Code Regulations.

The Code Act contains a schedule—the Agricultural and Veterinary Chemicals Code (the Agvet Code)—which sets out 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 applications 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 and the legislative instrument for modular assessment fees described below.

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 of assessment 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 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 imposition under 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.

The proposed new fees in relation to full cost recovery of the cost of compliance with GMP will be implemented by way of amendments to the Agvet Code Regulations and a small change to the Agvet Code.

In relation to the issue of a manufacturing licence, GMP audits demonstrating that the premises comply with the Manufacturing Principles will become a requirement 'prescribed by the regulations' that the APVMA must be satisfied has been complied with before a licence can be issued. As well, it will be a statutory licence condition under the Agvet Code Regulations that ongoing GMP audits will be necessary to provide continuing evidence that the licenced premises comply with the Manufacturing Principles.

For imported products, evidence that each product has been manufactured to a standard that is equivalent to the Manufacturing Principles will be required in order for the APVMA to be satisfied that the product should be registered in Australia. Additionally, it will be a condition of registration that ongoing evidence is provided when requested, that demonstrates compliance with a standard of manufacture that is equivalent with the Manufacturing Principles.

The new GMP Audit Assessment fees will be attached to these requirements by utilising s.164(1) of the Agvet Code and appropriate amendments to the Agvet Code Regulations.

The new Licence Application Fee will be directly attached to the application for a licence via s.122(1)(d) of the Agvet Code.

1.8 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.

The wholesale value of veterinary product sales tends to be relatively stable, whereas the wholesale value of agricultural product sales is closely linked to climatic conditions. Periods of lower-than-average rainfall or drought result in lower agvet chemical use and this directly causes lower levy revenue in the following year.

1.9 The APVMA's financial reserve

The APVMA's revenue can vary significantly from year-to-year as a result of fluctuations in sales of agvet chemicals due to changing environmental conditions.

To manage this, the APVMA aims to hold a financial reserve (which forms part of its equity). Without this financial reserve the APVMA would risk periods where its liabilities would exceed its assets (negative equity).

The financial reserve is based on three months of operating expenses and is currently set at $7.0 million.

2 THE APVMA'S ACTIVITIES

2.1 Introduction

This section outlines the APVMA's activities and cost recovery arrangements. A summary of the APVMA's activities is shown in Table 1 below.

TABLE 1: THE APVMA'S ACTIVITIES

ACTIVITIES		RELEVANCE TO APVMA
Pre-market regulation activities	A. REGISTRATION AND APPROVALS (SECTION 2.2)	• Registration and Approvals—evaluation of applications (including permits) • Re-registration and re-approval (from 1 July 2013) • Good Manufacturing Practice (GMP) compliance—evaluation of applications compliance • Certificates of Export • Consents to Import
	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)	• Assessment of GMP compliance audits • Hormonal Growth Promotant Scheme • Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (Ag QA Scheme) • Adverse Experience Reporting Program (AERP) • Chemical Review
	D. INVESTIGATION AND ENFORCEMENT (SECTION 2.4)	• Compliance and enforcement
Information activities	E. INFORMATION ACTIVITIES (SECTION 2.5)	• Website • Corporate publications • Presentations and seminars • Consultative committees • Informing policy

Each of the APVMA's activities is detailed in the following pages.

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. A diagram illustrating product registration is shown at Figure 1.

When an application for registration is submitted, the APVMA first analyses the data package for completeness of the data, any inconsistencies, and whether the level of detail is sufficient for an adequate risk assessment to be performed. 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, users, consumers and the environment. The evaluation also has to demonstrate that the product is suitably formulated, and that its label contains adequate instructions for safe and effective use. The APVMA must also assess whether using the product may unduly prejudice trade.

The costs of registrations and approvals are generally recovered through a combination of application fees and the levy, with most of the costs recovered through the levy. The Australian Government, states and territories agreed when establishing the NRS that the costs of assessing applications should be collected in two parts: 40 per cent of the assessment costs being charged as an upfront application fee and the balance of revenue required to fund the APVMA's costs covered by the levy on the annual value of sales described in section 3.3. The policy intent is to ensure that the application fee to assess and register new and innovative products is not a disincentive to bringing them into the market, particularly for small businesses, niche products and chemical products that have a low value of sales. It also acts as a balancing factor to buffer the APVMA budget against changes in application volumes and sales values.

Because application fees are not indexed the actual rate of recovery has fallen well below the 40 per cent recovery target for many application categories. The current cost recovery rate is averaging around 24.7 per cent with the remainder recovered through the levy. One of the aims of this CRIS is to document the restoration of application fees to 40 per cent cost recovery level. This is discussed in Section 3.

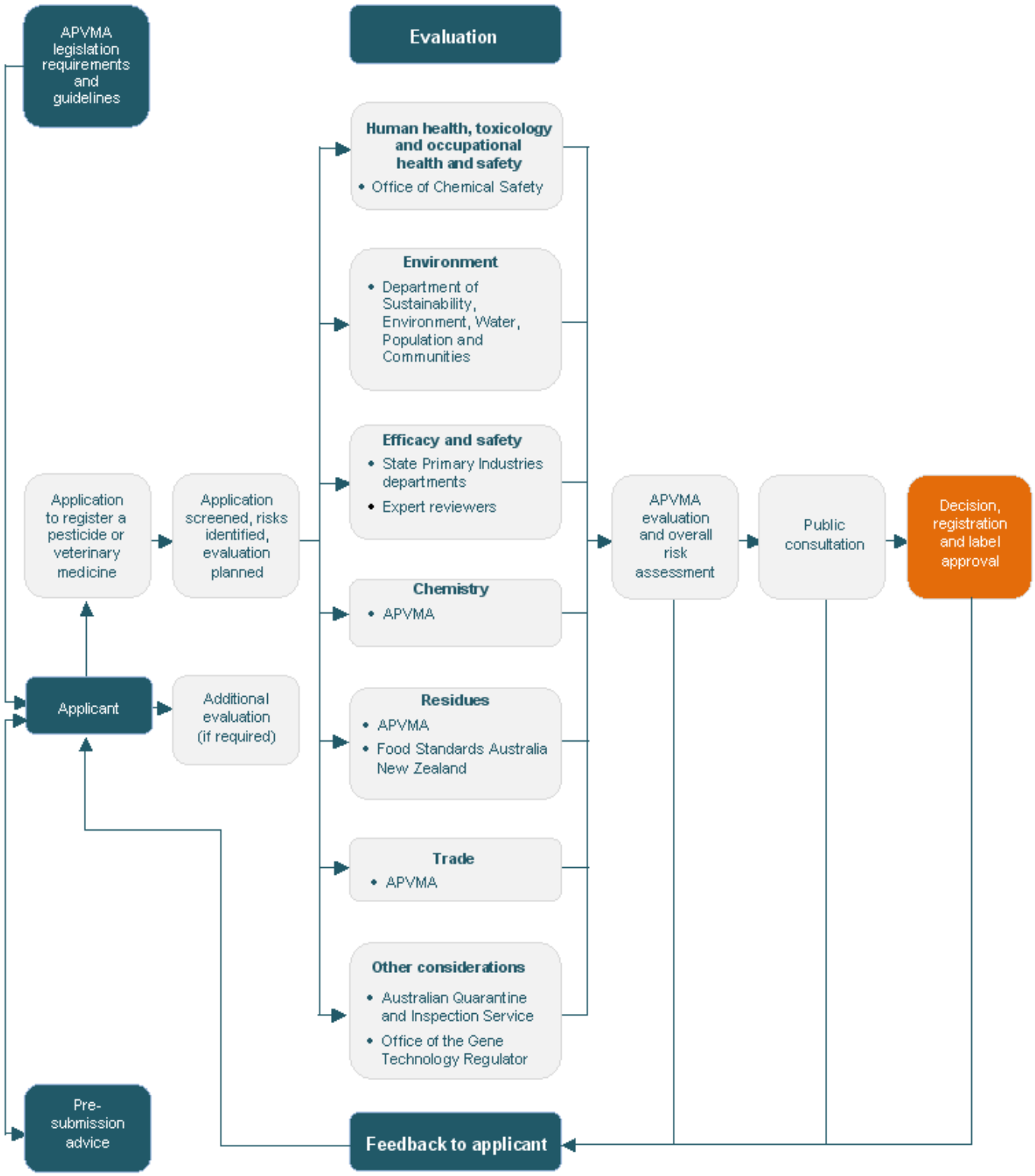
The 2011-12 costs of the registration and approvals activities are shown in Table 2 below.

TABLE 2: COST COMPONENTS OF REGISTRATION AND APPROVALS 2011–12 COSTS*

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST ($)
ACTIVITY: REGISTRATION AND APPROVALS			
Employee expenses	Technical and administrative assessment costs	Direct cost	7 996 128
Suppliers	Outsourced activities—scientific assessment services undertaken by external agencies	Direct cost	4 083 830
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	8 643 010
Total			**20 722 968**

*Not including the Re-registration and Re-approval Scheme

FIGURE 1: PROCESS MAP FOR PRODUCT REGISTRATIONS



Category 1-10 applications

Categories 1–10 are for registration of new products. Category 1 and 2 applications also include the approval of an active constituent. Details of the difference between these categories can be found in Table 19.

These application categories are cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

Category 11, 12 & 14 applications

Categories 11, 12 and 14 are applications to vary a registration or label approval. Further details can be found in Table 19.

These application categories are cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

Category 13 applications

Category 13 applications are for minor changes to particulars or conditions of registrations or label approvals that are required by the APVMA. They represent approximately 5 per cent of 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 creates incentives for registrants to avoid making these applications, which will eventually result in increased costs of compliance activities for the APVMA to be certain that revisions to manufacture etc are being made. Failure to make these applications also reduces the accuracy of APVMA records, which could detract in the level of community confidence in the regulatory framework.

There is no charge for this application category. The cost of processing these applications is funded by the annual fee.

Category 13A applications

Category 13A applications are for changes to relevant particulars of an approval or registration where the relevant particular is set out in a legislative instrument made for section 26A of the Agvet Code. The legislative instrument is expected to be in place before the commencement of the CRIS.

This category is cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

Category 15 and 16 applications (new active constituent)

Category 15 and 16 applications are for approval of new active constituents that require a full assessment. These applications are generally linked to a product application.

This application category is cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

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

Category 17 applications are 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.

This application category is cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

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

Category 18 applications are for varying particulars or conditions of an approved active constituent.

This application category is cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

Category 19–21 (permits)

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.

Permit applicants 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. These permits therefore attract only a nominal fee with the balance of costs funded through the levy.

Australian and state/territory government agencies also pay the 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 is an exemption 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 and activities that attract intellectual property of a value that may later be sold for profit or are conducted on a fee for service basis.

Category 22 (Emergency Use permits)

Emergency use permits are for situations where the proposed use is generally unforeseen (not seasonal, annual or on another regular basis) such as the outbreak of an exotic pest or disease or where unusual weather patterns have caused higher or more frequent pest or disease incursions.

Emergency uses may involve either the use of an existing registered agricultural product ‘off-label’ or the use of an unregistered agricultural or veterinary chemical product.

This application category has no fee and is funded by 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 and the details of these permits are not displayed on the public permits database.

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.

This application category is cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

Category 24 & 25 applications

Category 24 and 25 applications are for any other assessment that is not covered by categories 1–23.

These application categories are cost recovered under the policy of a 40 per cent recovery through the fee with the remaining costs funded by the levy.

Pre-application assistance (for products, active constituents and permits)

The Better Regulation of Agricultural and Veterinary Chemicals reforms introduce, through amendments to the Code Regulations, provision of pre-application advice to applicants by the APVMA relating to product registrations, active constituent approvals and permit applications.

Applicants will be encouraged to seek pre-application advice on the applications that they are preparing to clarify data requirements etc. Advice provided may include assistance with the selection of the correct category for the application together with advice on the data requirements for an application.
Pre-application advice will be provided in writing and in some circumstances may involve a face-to-face meeting or teleconference between the potential applicant and staff from the APVMA and advising agencies.

The cost of pre-application advice will be met by a fee, some of which may be rebated from a fee for a future application, as described in section 3.5.

Re-registration and re-approval scheme

The Better Regulation suite of reform introduces a scheme of re-registration of agvet chemical products and re-approval of active constituents. The scheme is expected to commence on 1 July 2013.
The scheme aims to ensure that existing agvet chemical products remain safe and efficacious and also consider any new information that may have become available since the time when a chemical was originally approved or registered.

All agvet chemical products and active constituents will be considered through the scheme. Products will be grouped according to their active constituent(s) and products and active constituents will enter the scheme in a sequence based on risk (identified through a matrix of criteria).

Registrants and approval holders will need to make an application to have their products and active constituents considered in the scheme. Where there is no application made to re-register a product or re-approve an active constituent, the registrations and approvals will expire and can no longer be supplied to the Australian marketplace. Products and active constituents that satisfy the criteria in the scheme will be re-registered and re-approved, respectively. Where there is some doubt that products and active constituents meet contemporary standards, these will be forwarded to the chemical review process where the potential concerns can be considered in detail.

The cost of re-registration/re-approval applications will be met by a combination of fee and levy as described in section 3.5.

Evaluation of applications for Good Manufacturing Practice (GMP)

The *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) provides that veterinary products manufactured in Australia must be manufactured in premises which are GMP compliant. This does not apply to agricultural chemical products.

GMP compliance is assessed through two schemes: the Manufacturers' Licensing Scheme (MLS) for Australian manufacturers and the Overseas GMP Scheme for products manufactured overseas and imported into Australia.

The MLS ensures that veterinary products are manufactured to an approved standard through a quality assurance scheme based on GMP. The MLS requires that anyone involved in any step of manufacture of a veterinary product in Australia is appropriately licensed by the APVMA for the step(s) performed, unless exempt under the regulations[2]. A licence will be issued after an Australian applicant manufacturer demonstrates compliance with GMP requirements through an initial audit conducted by an APVMA-authorised GMP auditor and by taking any necessary corrective action identified in the audit.

The main costs incurred by the APVMA in maintaining the MLS is in the initial assessment of the licence application under the MLS, consideration of an initial audit report to decide whether a licence should be issued in the first instance, and consideration of subsequent audit reports.

The Overseas GMP Scheme ensures that registrants of veterinary products manufactured overseas obtain and maintain evidence that the products are manufactured in accordance with a standard at least equivalent to the APVMA's requirements. This evidence is required upon application for registration or changes to the overseas sites of manufacture and thereafter provided upon request to the APVMA as a condition of registration.

For imported products under the Overseas GMP Scheme, costs are incurred with the initial and ongoing assessments of evidence of GMP compliance of the overseas manufacturer. All domestic and those foreign manufacturers who cannot provide suitable evidence of GMP compliance are required to undergo regular audits by APVMA authorised auditors.

Table 3 provides the 2011–12 costs for the GMP compliance assessment schemes.

2 Regulation 59, 59A-D of the *Agricultural and Veterinary Chemicals Code Regulations 1995.*

TABLE 3: COST COMPONENTS OF GMP COMPLIANCE ASSESSMENT 2011–12

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST ($)
ACTIVITY: GMP COMPLIANCE ASSESSMENT SCHEMES			
Employee expenses	Assessment of MLS licences and imported products for GMP compliance; and management of GMP auditing.	Direct cost	741 799
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	713 227
Total			**1 455 026**

Certificates of Export

Before accepting exports of an agvet product from Australia, many countries require an assurance from the APVMA that the export chemical is suitable for supply and use. Section 69D of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* gives the APVMA the legislative power to issue a certificate of export for an agvet product.

Those who wish to obtain a Certificate of Export are charged a direct fee for this service. This fee is being maintained without change, as discussed in section 3.2.

Table 4 provides the 2011–12 costs for Certificates of Export.

TABLE 4: COST COMPONENTS OF CERTIFICATES OF EXPORT 2011–12

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST ($)
ACTIVITY: CERTIFICATES OF EXPORT			
Employee expenses	Assessment of compliance with GMP and administrative services	Direct cost	36 646
Suppliers	Not applicable	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	42 761
Total			**79 407**

Consents to Import

A person must not import into Australia an unregistered agvet product or unapproved active constituent, unless it has either been exempted from the importation provisions or the importer has obtained written consent from the APVMA[3]. Consent is issued under limited circumstances, for example to veterinarians for use of the product on animals under their care or where an APVMA Permit covers the supply or use of such a product.

Charging a fee for consents will act as a disincentive to the lodgement of applications and this will be inconsistent with policy goals. Accordingly, no fee is charged for this service. The Consent to Import activity is funded via the Annual Fee.

Table 5 provides the 2011–12 costs for Consent to Import.

[3] Section 69(B) of the *Agricultural and Veterinary (Administration) Act 1992*.

TABLE 5: COST COMPONENTS OF CONSENT TO IMPORT ACTIVITIES 2011-12

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST ($)
ACTIVITY: CONSENT TO IMPORT			
Employee expenses	Consent to Import assessment	Direct cost	134 482
Suppliers	Not applicable	Not applicable	Not available
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	156 923
Total			**291 405**

2.3 Monitoring ongoing compliance with regulations

Hormonal Growth Promotant (HGP) Scheme

The APVMA is responsible for controlling the supply of HGPs within the National HGP Control and Monitoring System managed by DAFF biosecurity (formerly the Australian Quarantine and Inspection Service). The system was introduced in 1993 in response to demands by the European Union 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. Suppliers are required to provide the APVMA with details of all acquisitions and disposals of HGPs on a monthly basis and details are recorded in a database.

The HGP scheme is funded through a direct fee to users of the service. This fee is being maintained without change, as discussed in section 3.2.

Table 6 provides the 2011–12 costs for the HGP Scheme.

TABLE 6: COST COMPONENTS OF THE HGP SCHEME 2011-12

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	43 845
Suppliers	Not applicable	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	51 161
Total			**95 006**

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 that set out the purity of the active constituent and the maximum allowable impurity level. The *Conditions of*

Registration for agricultural 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 product formulators to monitor compliance with the *Conditions of Registration*. The Ag QA scheme has been an important tool in strengthening industry practices in overseeing the sourcing of raw materials and their use in the manufacture and formulation of agricultural products.

The cost of the Ag QA Scheme is recovered via the Annual Fee, as discussed in Section 3.2.

Table 7 provides the 2011-12 costs of the Ag QA Scheme.

TABLE 7: COST COMPONENTS OF THE AG QA SCHEME 2011–12

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST ($)
ACTIVITY: Ag QA SCHEME			
Employee expenses	Audit (record inspections) and testing	Direct cost	75 648
Suppliers	Not available	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	88 273
Total			**163 921**

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

The AERP is the main mechanism for the APVMA to receive and consider stakeholder and public feedback on adverse experiences relating to the use of agvet chemicals. The AERP provides post-registration surveillance that helps the responsible marketing and management of agvet chemicals throughout their life. The AERP provides the APVMA with feedback about the quality, safety and efficacy of agvet chemicals in the field. This information helps to ensure that the APVMA's registration decisions are appropriate.

The Chemical Review Program reconsiders the registration of agvet chemicals if potential risks to safety and performance have been identified. Reviews may focus on one or more areas of concern including environmental safety, worker safety, public health, residues or trade, or less commonly, may consider product efficacy. It operates independently of the Re-registration and re-approval scheme.

The Program aims to ensure that chemicals approved for sale and use in Australia can continue to be used safely and effectively. Reviews are undertaken on a priority basis in cases where credible safety and/or efficacy concerns have been identified. A chemical review can affect one or more active constituent approvals of a chemical, registration of products containing the chemical, and/or relevant label particulars on product containers. Any of these may be reconsidered more than once.

All registrants benefit from the AERP and Chemical Review Programs. The programs also promote and maintain public confidence in the National Registration Scheme (NRS).

The cost of both these programs is recovered through the levy, discussed in section 3.4.

Table 8 provides the 2011–12 costs for the AERP and Chemical Review.

TABLE 8: COST COMPONENTS OF THE AERP AND CHEMICAL REVIEW 2011–12

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST ($)
ACTIVITY: AERP AND CHEMICAL REVIEW			
Employee expenses	Review work, AERP	Direct cost	1 111 918
Suppliers	Outsourced activities—scientific assessment services by external agencies	Direct cost	375 172
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	1 009 703
Total			**2 496 793**

2.4 Investigation and enforcement

The APVMA assesses and investigates claims that agvet chemicals may not be compliant with 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 cost of investigation and enforcement should be borne by registrants and approval holders as it is their responsibility to supply a product that is registered or approved and that complies with the conditions of registration or approval. All registrants of agvet chemicals benefit from investigation and enforcement activities.

Costs for these activities are recovered through the Annual Fee, as discussed in section 3.2.

Table 9 provides the 2011–12 costs for investigation and enforcement.

TABLE 9: COST COMPONENTS OF INVESTIGATION AND ENFORCEMENT 2011–12

EXPENSE	INCLUSIONS	ATTRIBUTION	ANNUAL COST ($)
ACTIVITY: INVESTIGATION AND ENFORCEMENT			
Employee expenses	Non-compliance report processing, product recalls and investigations	Direct cost	954 803
Suppliers	Not applicable	Not applicable	Not applicable
Overheads	Refer to Appendix A for list of overhead costs	Indirect cost	1 114 139
Total			**2 068 942**

The December 2011 Cost Recovery Discussion Paper outlined proposed increases to the APVMA's compliance and enforcement resource base to allow full use of the more modern, graduated compliance system being implemented under the Better Regulation of Agricultural and Veterinary Medicines reforms. The increased resources will allow the full suite of compliance tools to be utilised.

Five additional compliance staff will be recruited. The estimated future additional costs are shown in Table 10 below.

TABLE 10: ADDITIONAL COMPLIANCE AND ENFORCEMENT COSTS

COMPLIANCE AND ENFORCEMENT	2012-13	2013-14	2014-15
Additional compliance and enforcement	-	771 338	814 289

2.5 Information activities

The APVMA provides information on agvet regulatory arrangements through the APVMA website, corporate publications, consultative committees, and presentations and seminars. The APVMA also assists in the development of policy and undertakes parliamentary servicing functions (such as attending Senate Estimates hearings, the provision of answers to Questions on Notice, the provision of ministerial briefings etc). These activities are integral to the effective management of the NRS.

The costs of these activities are recovered as overheads attributed to the various Programs of the APVMA as discussed in section 3.2.

3 COST RECOVERY ARRANGEMENTS APPLICABLE AFTER 1 JULY 2013

3.1 Introduction

This section outlines the APVMA's cost recovery arrangements to apply after 1 July 2013.

3.2 Components being maintained

No changes will be made to the existing direct fees for:

- Certificates of Export - the existing direct fee for this service remains sufficient to cover the costs of this activity.
- HGP - the existing direct fee for this service remains sufficient to cover the costs of this activity.

The annual fee

The Annual Fee of $430 is payable by 31 May each year to maintain a product on the register for the following financial year. As detailed in Section 2, the fee previously funded the APVMA's compliance activities, the cost of processing category 13 applications and the costs associated with maintaining the product register. This cost recovery approach will continue and no change will be made to the existing Annual Fee—this is separate to the GMP Audit Assessment Fee.

An estimate of Annual Fee revenue is shown in Table 11 below.

TABLE 11: ESTIMATION OF 2012-13 TO 2014-15 ANNUAL FEE REVENUE

ANNUAL FEE	2012-13	2013-14	2014-15
Estimated number of products	10 200	10 475	10 737
Fee per product	430	430	430
Total ($)	**4 394 600**	**4 504 250**	**4 616 910**

Information activities

The costs of these activities will continue to be recovered as overheads attributed to the various Programs of the APVMA. 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.

3.3 The need for changes to the cost recovery arrangements

Through the ongoing monitoring of the performance of its cost recovery arrangements, APVMA identified the following issues with the cost recovery arrangements as follows:

- Cost recovery for product evaluations have fallen below the policy target of 40 per cent recovery through upfront application fees. The recovery rate is currently averaging around 24.7 per cent with the remaining costs funded through the levy.

- GMP compliance assessment costs have been under-recovered and only a small proportion of the total cost of assessment of GMP compliance has been recovered through the MLS licence fees.

Additionally, there are a number of activities flowing from the introduction of the Better Regulation of Agricultural and Veterinary Chemicals reforms that require changes to the APVMA's cost recovery arrangements in the form of new fees:

- an application fee for Re-registration and Re-approval (previously called 'Continuation' in the December 2011 Cost Recovery Discussion Paper)
- a new fee for pre-application assistance (see discussion at section 3.5 below)
- a new fee for conversion of non-electronic applications to an electronic format (when applications are provided to the APVMA in hard copy). The fee is $90 per hour.

3.4 The levy

Registrants of agvet products pay levies based on the dollar value of sales (disposals) on their registered products. Each year registrants are required to provide the APVMA with the dollar value of sales by completing a request for leviable values. A levy is payable on all sales for each product greater than $5 000. The current levy tiers are as follows:

- 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 APVMA commissions independent audits of the leviable values declarations, checking reported sales against company financial records, to ensure they are accurate.

As a result of the restoration of application fees to 40 per cent together with the full cost recovery of compliance with GMP, the levy rates applicable during this CRIS period are reduced as shown in Table 12 below. No change will be made to levy tiers (thresholds).

TABLE 12: LEVY RATES

	(CURRENT RATES)		
LEVY PAID IN	2012-13	2013-14	2014-15
BASED ON SALES DURING	2011-12	2012-13	2013-14
Levy tier 1 (annual product sales up to $1 000 000)	0.80%	0.70%	0.63%
Levy tier 2 (annual product sales between $1 000 001 and $5 000 000)	0.45%	0.40%	0.35%
Levy tier 3 (annual product sales greater than $5 000 000)	0.30%	0.28%	0.25%

3.5 Registration and approvals

This CRIS reflects changes to the APVMA's cost recovery arrangements in order to restore the original policy intent established by the Australian Government, states and territories in setting up the NRS that 40 per cent of the costs of assessing applications should be recovered as an upfront application fee with the remaining costs funded by the levy on the annual value of sales.

This policy will continue to apply to cost recovery fees for categories 1–25 (including modules 1–12). However, as noted in Section 2.2, cost recovery level for product evaluations has fallen well below the agreed NRS policy target of 40 per cent recovery for many categories of application fees. This CRIS outlines how the restoration of the cost recovery level for these product applications to 40 per cent will be implemented. To cushion the increase, implementation will occur in three phases:

- phase one—an increase of all fees to at least 30 per cent of the cost of undertaking the associated activities from 1 July 2013;
- phase two—an increase of all fees to 35 per cent of the cost of undertaking the activity from 1 July 2014; and
- phase three—an increase of all fees to 40 per cent of the cost of undertaking the activity from 1 January 2015.

Re-registration and Re-approval

The Better Regulation of Agricultural and Veterinary Chemicals reforms introduced a Re-registration and Re-approval scheme. From 1 July 2013, there will be a $700 application fee for re-registration and re-approval based on the technical and administrative work required to process the application, as proposed in the December 2011 Cost Recovery Discussion Paper. This fee is based on estimates that $700 will recover 40 per cent of the cost of the service with the remaining 60 per cent funded through the levy, consistent with the established NRS policy for other application fees.

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 through the levy.

The estimated costs associated with the Re-registration and Re-approval Scheme are shown at Table 13 below.

TABLE 13: ESTIMATED COST COMPONENTS OF RE-REGISTRATION AND RE-APPROVAL 2013-14 TO 2015-16

EXPENSE	INCLUSIONS	ATTRIBUTION	2013-14 ($)	2014-15 ($)	2015-16 ($)
ACTIVITY: RE-REGISTRATION AND RE-APPROVAL					
Employee expenses	Technical and administrative assessment costs	Direct cost	574 554	1 030 734	1 549 764
Suppliers	Outsourced activities—scientific assessment services by external agencies	Direct cost		200 000	400 000
Total			**574 554***	**1 230 734***	**1 949 764***

* This CRIS covers the period 2013-14 – 2014-15. The 2015-16 costs are provided as the scheme will be scaled up over a 3 year period. The 2015-16 costs indicate the ongoing expenses of the scheme).

Pre-application advice (for products, active constituents and permits)

The Better Regulation of Agricultural and Veterinary Chemicals reforms introduce, through amendments to the Code Regulations, a fee for the provision of pre-application advice to applicants by the APVMA. Fees are charged for advice relating to product registrations, active constituent approvals and permit applications.

The initial fee payable for pre-application advice is $350 reflecting staff time to review, research and attend meetings. Additional cost units of $175/person/hour will be added to the initial fee, based on the time taken to prepare and provide the advice and the number of advising agencies that are required to be involved in provision of the advice.

Applicants will be encouraged to seek pre-application advice on the applications that they are preparing to clarify data requirements etc. The cost of the activity is fully recovered from the applicant, however a rebate is provided if the applicant proceeds to lodge an application. The rebate varies according to the category of the application, as set out in Table 14. The rebate is provided in recognition that the pre-application advice will improve the quality of applications. Better quality applications will in-turn improve the efficiency of the evaluation process. The rebates have been determined according to the complexity of the advice likely to be sought for particular categories. Advice provided may include assistance with the selection of the correct category for the application together with advice on the data requirements for an application. Pre-application advice will be provided in writing and in some circumstances may involve a face-to-face meeting or teleconference between the potential applicant and staff from the APVMA and advising agencies.

The rebates are shown in Table 14 below.

TABLE 14: PRE-APPLICATION ADVICE – REBATES FROM 1 JULY 2013

CATEGORY	FEE
1, 2, 15	$ 1 400
3, 4, 11	$ 1 050
5, 6, 16, 17, 18	$ 700
7, 8, 9, 10, 12, 14, 19, 20, 21, 22, 23, 24	$ 350
13, 13A, 25, re-registration and re-approval	**Nil**

Conversion of applications to electronic format

The Better Regulation of Agricultural and Veterinary Chemicals reforms introduce, through amendments to the Regulations, a fee for conversion of non-electronic applications to an electronic format (when applications are provided to the APVMA in hard copy). The fee is $90 per hour based on the anticipated cost of processing the documents.

3.6 Good Manufacturing Practice

The existing Manufacturers' Licensing Scheme (MLS) licence fees only recover a small proportion of the total operating cost of the program. In 2011–12, the cost of operating the Manufacturing Quality and Licensing (MQL) Section was $1 471 575. The revenue received through licence fees over the same period was $26 400 for the year, leaving a shortfall of $1 445 175.

A Supplementary Discussion Paper on Cost Recovery for Good Manufacturing Practice was published in May 2012. This paper proposed a range of fees to allow the full cost recovery of GMP activities. The proposals outlined in the discussion paper were supported by key industry groups.

This CRIS outlines the fees that will apply from 1 July 2013. An annual GMP Audit Assessment Fee will be introduced to recover the cost of monitoring, timely conduct and closure of all audits for Australian-based manufacturers, preparing pre-audit information for auditors, reviewing audit reports, addressing disputes, answering manufacturer queries, updating licences for routine changes (such as changes to personnel), and where necessary initiating compliance/enforcement action.

A GMP Audit Assessment Fee of $7 500 per annum for manufacturers of sterile and immunobiological products (Category 1) will be introduced.

A GMP Audit Assessment Fee of $5 000 per annum for single-category manufacturers of Category 2 (non-sterile medicinal products), Category 3 (ectoparasiticides) or Category 4 (feed mixes and supplements) products will be introduced. Where a manufacturer performs manufacture of multiple categories of non-sterile products (Categories 2, 3, 4), a GMP Audit Assessment Fee of $7 500 per annum will apply. Single-step manufacturers (Category 6 licensees) will be charged a GMP Audit Assessment Fee of $1 800 per annum. These activities are undertaken on behalf of all Australian manufacturers, with audits of each manufacturer conducted approximately every 18 months. The veterinary manufacturing industry's strong preference was that the fee be applied every year at the same time, thus providing predictability.

Australian registrants of imported veterinary products will be charged a GMP Foreign Audit Assessment Fee of $1 000 for each foreign site of manufacture engaged in the manufacture of the products.

In addition, Australian manufacturers will be charged a Licence Application Fee of $900 for each new application for a licence submitted.

Finally, Australian manufacturers will be charged a Supplemental Audit Review Fee of $1 800, where the audit is conducted in response to a licensee's application to extend the scope of an existing licence, and is outside the usual cycle of periodic audits.

More information on how these fees were derived can be found in the Supplementary Cost Recovery Discussion Paper.

The GMP fees are shown in Table 15 below.

TABLE 15: GMP FEES AND CHARGES FROM 1 JULY 2013

TYPE	CATEGORY	NUMBER	FEE ($)	FEE REVENUE ($)
ACTIVITY: GMP COMPLIANCE ASSESSMENT SCHEMES – ANNUAL FEES				
Australian Manufacturers	GMP Audit Assessment Fee—Category 1 (Single and Multi-Category 1) and Multi-Category 2–4	80	7 500	600 000
Australian Manufacturers	GMP Audit Assessment Fee—Single Category 2–4	55	5 000	275 000
Australian Manufacturers	GMP Audit Assessment Fee—Category 6 (Single-step manufacture)	80	1 800	144 000
Australian Importers/Registrants (per registrant/site)	GMP Foreign Audit Assessment Fee	470 registrant sites [4]	1 000	470 000
ACTIVITY: GMP COMPLIANCE ASSESSMENT SCHEMES—LICENCE APPLICATION AND VARIOUS OTHER ADMINISTRATIVE FEES				
Australian Manufacturers	Licence Application Fee	23	900	20 700
Australian Manufacturers	Supplemental Audit Review Fee	2	1 800	3 600
Total				**1 513 300**

It is noteworthy that the full recovery of the costs of compliance with GMP will also allow a reduction in levy rates, which are shown at Table 12.

[4] Some overseas sites have multiple GMP compliance assessments for various reasons (eg for different registrants using the same site or for different/additional product types).

3.7 Forecast operating results of cost recovery arrangements

Table 16 below provides a summary of the forecast operating results for the next two years.

TABLE 16: FORECAST OPERATING RESULT 2012-13 TO 2014-15

	2012-13 ($)	2013-14 ($)	2014-15 ($)
Income	**30 837 249**	**31 858 702**	**32 108 655**
Less:			
Repayment of $2 million to government[5]	(500 000)	(1 500 000)	-
Total Income	**30 337 249**	**30 358 702**	**32 108 655**
Expense—Base	28 889 284	30 162 593	30 811 649
Add:			
Implementation of Reform Agenda[6]	2 755 176	2 344 482	-
Increase compliance and enforcement activities	-	771 338	814 289
Re-registration and re-approval scheme (on-going operation)		574 555	1 230 734
Total expenses	**31 644 460**	**33 852 968**	**32 856 672**
Surplus/(deficit)	**(1 307 211)**	**(3 494 266)**	**(748 017)**
Equity	**11 124 163**	**7 629 897**	**6 881 880**

As outlined in the Discussion Paper the Reform Agenda will result in efficiencies leading to savings for the APVMA. These savings will be used to offset reform costs, including additional evaluation resources to further improve timeframe performance.

3.8 Implementation

The revised application fees, fees for re-registration and re-approval, fees for pre-application advice, fee for conversion of non-electronic applications, reductions in the levy rates and new GMP fees and charges will commence from 1 July 2013. Application fee changes would apply to any new applications lodged from 1 July 2013 or, in the case of the levy, from the first collection period after the amendments to the regulations have commenced. Implementation dates are shown in Table 17 below.

[5] $2Mil of the $8.75 Mil of Better Regulation funding will be repaid to government in these years.

[6] The Reform Agenda has been funded by the $8.75 million received from the Government. The majority of this funding was received in 2010–11 and 2011–12. Unspent reform funding inflates Equity over the period 2011-2014. Further information on the implementation of the Reform Agenda can be found on the APVMA's website at www.apvma.gov.au

TABLE 17: IMPLEMENTATION DATES

REVISED ARRANGEMENTS	COMMENCEMENT
Application fees to a minimum 30% cost recovery	From 1 July 2013
Application fees to a minimum 35% cost recovery	From 1 July 2014
Application fees to a minimum 40% cost recovery	From 1 January 2015
Other fees and charges	From 1 July 2013
Levy rate change	From 1 July 2013, on sales made from 1 July 2012

3.9 Summary of cost recovery arrangements 2013-14 and 2014-15

Tables 18 and 19 below provide a summary of the APVMA's cost recovery arrangements for 2013–14 and 2014–15 respectively.

Further details of the costs of each category are shown at Appendix B (noting these costs reflect actual costs for 2011–12).

TABLE 18: COST RECOVERY ARRANGEMENTS 2013-14

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2013-14 COST RECOVERY VIA FEE ($)	2013-14 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[7] ($)	=A x B FORECAST TOTAL COST ($)
Category 1	Fee and levy	7	53 745	72 100	186 119	258 219	1 807 533
Category 2	Fee and levy	14	The modular assessment fee[8]	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 3	Fee and levy	4	34 925	48 465	125 114	173 579	694 316
Category 4	Fee and levy	3	23 330	27 505	71 003	98 508	295 524
Category 5	Fee and levy	41	3 630	3 655	9 427	13 082	536 362
Category 6	Fee and levy	92	2 470	3 220	8 306	11 526	1 060 392
Category 7	Fee and levy	367	660	1 315	3 398	4 713	1 729 671
Category 8	Fee and levy	186	595	1 250	3 220	4 470	831 420
Category 9	Fee and levy	4	545	1 195	3 094	4 289	17 156

[7] Cost per event or application.

[8] The cost of an assessment under modular categories (categories 2, 10, 14, 24 & 25) is the sum of the cost of each of the required modular items.

TABLE 18: COST RECOVERY ARRANGEMENTS 2013-14

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2013-14 COST RECOVERY VIA FEE ($)	2013-14 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[7] ($)	=A x B FORECAST TOTAL COST ($)
Category 10	Fee and levy	182	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 11	Fee and levy	4	15 685	21 460	55 394	76 854	307 416
Category 12	Fee and levy	726	615	875	2 262	3 137	2 277 462
Category 13	Annual Fee	171	Nil fee	-	4 771	4 771	815 841
Category 13A	Fee and levy	-	385	-	-	-	-
Category 14	Fee and levy	688	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 15	Fee and levy	6	25 775	25 775	56 284	82 059	492 354
Category 16	Fee and levy	1	4 430	14 105	36 405	50 510	50 510
Category 17	Fee and levy	96	1 580	2 365	6 106	8 471	813 216
Category 18	Fee and levy	15	1 005	1 850	4 770	6 620	99 300
Category 19	Fee and levy	31	350	350	2 554	2 904	90 024
Category 20	Fee and levy	287	350	350	2 554	2 904	833 448
Category 21	Fee and levy	134	350	350	2 554	2 904	447 216
Category 22	Levy	57	Nil fee	-	2 904	2 904	165 528
Category 23	Fee and levy	135	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 24	Fee and levy	4	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 25	Fee and levy	7	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee

TABLE 18: COST RECOVERY ARRANGEMENTS 2013-14

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2013-14 COST RECOVERY VIA FEE ($)	2013-14 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[7] ($)	=A x B FORECAST TOTAL COST ($)
Module 1	Fee and levy	1 018 [9]	505	535	1 373	1 908	1 942 344
Module 2.1	Fee and levy	7 [9]	3 255	6 915	17 844	24 759	173 313
Module 2.2	Fee and levy	7 [9]	2 230	2 305	5 955	8 260	57 820
Module 2.3	Fee and levy	103 [9]	1 030	1 185	3 057	4 242	436 926
Module 2.4	Fee and levy	182 [9]	200	570	1 474	2 044	372 008
Module 3.1	Fee and levy	2 [9]	19 490	20 940	54 055	74 995	149 990
Module 3.2	Fee and levy	3 [9]	14 620	14 620	27 801	42 421	127 263
Module 3.3	Fee and levy	42 [9]	2 900	3 035	7 837	10 872	456 624
Module 4	Fee and levy	8 [9]	3 720	2 435	4 106	6 541	52 328
Module 5.1	Fee and levy	2 [9]	5 595	13 630	35 177	48 807	97 614
Module 5.2	Fee and levy	13 [9]	4 765	7 895	20 372	28 267	367 471
Module 5.3	Fee and levy	2 [9]	2 490	6 150	15 874	22 024	44 048
Module 5.4	Fee and levy	20 [9]	2 230	5 600	14 456	20 056	401 120
Module 5.5	Fee and levy	1 [9]	1 175	1 500	3 872	5 372	5 372
Module 6.1	Fee and levy	2 [9]	4 310	4 310	7 530	11 840	23 680
Module 6.2	Fee and levy	27 [9]	2 900	2 900	5 652	8 552	230 904
Module 6.3	Fee and levy	6 [9]	1 435	2 985	7 700	10 685	64 110

[9] The volumes recorded against each of the modules represent the number completed when undergoing the assessment of the modular categories only

TABLE 18: COST RECOVERY ARRANGEMENTS 2013-14

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2013-14 COST RECOVERY VIA FEE ($)	2013-14 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[7] ($)	=A x B FORECAST TOTAL COST ($)
Module 7.1	Fee and levy	2 [9]	12 605	19 795	51 095	70 890	141 780
Module 7.2	Fee and levy	8 [9]	3 255	5 485	14 162	19 647	157 176
Module 7.3	Fee and levy	8 [9]	620	1 290	3 337	4 627	37 016
Module 8.1	Fee and levy	25 [9]	1 865	1 865	4 497	6 362	159 050
Module 8.2	Fee and levy	96 [9]	750	750	1 871	2 621	251 616
Module 8.3	Fee and levy	82 [9]	500	500	1 056	1 556	127 592
Module 9	Fee and levy	- [9]	1 175	1 175	-	1 175	-
Module 10.1	Levy	- [9]	Nil fee	-	-	-	-
Module 10.2	Levy	2 [9]	Nil fee	-	-	-	-
Module 10.3	Levy	2 [9]	Nil fee	-	-	-	-
Module 11.1	Fee and levy	53 [9]	2 230	3 040	7 849	10 889	577 117
Module 11.2	Fee and levy	181 [9]	1 175	1 175	2 972	4 147	750 607
Module 11.3	Fee and levy	- [9]	620	645	1 674	2 319	-
Module 11.4	Fee and levy	674 [9]	160	570	1 462	2 032	1 369 568
Module 12	Fee and levy	265 [9]	170	345	886	1 231	326 215
GMP Audit Assessment Fee - Category 1 and Multi-Category 2-4	Fee	80	N/a	7 500	225	7 725	617 977
GMP Audit Assessment Fee - Single Category 2-4	Fee	55	N/a	5 000	150	5 150	283 239

TABLE 18: COST RECOVERY ARRANGEMENTS 2013-14

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2013-14 COST RECOVERY VIA FEE ($)	2013-14 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[7] ($)	=A x B FORECAST TOTAL COST ($)
GMP Audit Assessment Fee - Category 6	Fee	80	N/a	1 800	54	1 854	148 314
GMP Foreign Assessment Fee	Fee	470	N/a	1 000	30	1 030	484 082
GMP Licence Application Fee	Fee	23	N/a	900	27	927	21 320
GMP Supplement Audit Review Fee	Fee	2	N/a	1 800	54	1 854	3 708
Certificate of Export (no technical assessment)	Fee	295	125	125		172	50 740
Certificate of Export (requires technical assessment)	Fee	110	230	230		310	34 100
HGP Notification number application and renewal	Fee	361	305	305		295	96 465
Investigation and enforcement	Annual fee	N/a	N/a	3 480 804	0	3 480 804	3 480 804

TABLE 18: COST RECOVERY ARRANGEMENTS 2013–14

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2013–14 COST RECOVERY VIA FEE ($)	2013–14 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[7] ($)	=A x B FORECAST TOTAL COST ($)
Chemical Review and AERP	Levy	N/a	N/a	0	2 829 592	2 829 592	2 829 592
Other expenditure[10]	Other income and levy	N/a	N/a	354 212	264 017	618 229	618 229
Implementation of the reforms	Funded via Gov't Approp	N/a	N/a	2 344 482		2 344 482	2 344 482
Establishment of re-registration and re-approval scheme	Fee and levy	N/a	N/a	-[11]	574 555	574 555	574 555
Total cost of activities							**33 852 968**
Deficit funded by equity	Equity						- 3 494 266
Total income							**30 358 702**

[10] Other expenditure includes: the setting of maximum residue limits (MRLs) for agricultural and veterinary chemicals (on-going); the write-off of outstanding GMP licence debts (one-off); as well as various ad hoc fully funded projects.

[11] There is no re-registration or re-approval fee income in 2013–14 as the first intact of chemicals will not be until 2014–15.

TABLE 19: COST RECOVERY ARRANGEMENTS 2014-15

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2014-15 COST RECOVERY VIA FEE ($)	2014-15 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[12] ($)	=A x B FORECAST TOTAL COST ($)
Category 1	Fee and levy	7	53 745	84 115	181 377	265 492	1 858 444
Category 2	Fee and levy	14	The modular assessment fee[13]	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 3	Fee and levy	4	34 925	56 545	121 923	178 468	713 872
Category 4	Fee and levy	3	23 330	32 090	69 192	101 282	303 846
Category 5	Fee and levy	41	3 630	4 260	9 191	13 451	551 491
Category 6	Fee and levy	92	2 470	3 755	8 096	11 851	1 090 292
Category 7	Fee and levy	367	660	1 535	3 311	4 846	1 778 482
Category 8	Fee and levy	186	595	1 455	3 141	4 596	854 856
Category 9	Fee and levy	4	545	1 395	3 015	4 410	17 640
Category 10	Fee and levy	182	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 11	Fee and levy	4	15 685	25 035	53 984	79 019	316 076
Category 12	Fee and levy	726	615	1 020	2 206	3 226	2 342 076
Category 13	Annual Fee	171	Nil fee	-	4 906	4 906	838 926
Category 13A	Fee and levy	-	385	-	-	-	-

[12] Cost per event or application

[13] The cost of an assessment under modular categories (categories 2, 10, 14, 24 & 25) is the sum of the cost of each of the required modular items.

TABLE 19: COST RECOVERY ARRANGEMENTS 2014-15

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2014-15 COST RECOVERY VIA FEE ($)	2014-15 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[12] ($)	=A x B FORECAST TOTAL COST ($)
Category 14	Fee and levy	688	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 15	Fee and levy	6	25 775	26 730	57 641	84 371	506 226
Category 16	Fee and levy	1	4 430	16 455	35 478	51 933	51 933
Category 17	Fee and levy	96	1 580	2 760	5 950	8 710	836 160
Category 18	Fee and levy	15	1 005	2 155	4 651	6 806	102 090
Category 19	Fee and levy	31	350	350	2 635	2 985	92 535
Category 20	Fee and levy	287	350	350	2 635	2 985	856 695
Category 21	Fee and levy	134	350	350	2 635	2 985	459 690
Category 22	Levy	57	Nil fee	-	2 985	2 985	170 145
Category 23	Fee and levy	135	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 24	Fee and levy	4	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Category 25	Fee and levy	7	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee	The modular assessment fee
Module 1	Fee and levy	1 018 [14]	505	620	1 341	1 961	1 996 298
Module 2.1	Fee and levy	7 [14]	3 255	8 065	17 391	25 456	178 192
Module 2.2	Fee and levy	7 [14]	2 230	2 690	5 802	8 492	59 444

[14] The volumes recorded against each of the modules represent the number completed when undergoing the assessment of the modular categories only

TABLE 19: COST RECOVERY ARRANGEMENTS 2014-15

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2014-15 COST RECOVERY VIA FEE ($)	2014-15 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[12] ($)	=A x B FORECAST TOTAL COST ($)
Module 2.3	Fee and levy	103 [14]	1 030	1 380	2 981	4 361	449 183
Module 2.4	Fee and levy	182 [14]	200	665	1 437	2 102	382 564
Module 3.1	Fee and levy	2 [14]	19 490	24 430	52 678	77 108	154 216
Module 3.2	Fee and levy	3 [14]	14 620	14 620	28 996	43 616	130 848
Module 3.3	Fee and levy	42 [14]	2 900	3 540	7 638	11 178	469 476
Module 4	Fee and levy	8 [14]	3 720	3 720	3 005	6 725	53 800
Module 5.1	Fee and levy	2 [14]	5 595	15 900	34 282	50 182	100 364
Module 5.2	Fee and levy	13 [14]	4 765	9 210	19 853	29 063	377 819
Module 5.3	Fee and levy	2 [14]	2 490	7 175	15 469	22 644	45 288
Module 5.4	Fee and levy	20 [14]	2 230	6 535	14 086	20 621	412 420
Module 5.5	Fee and levy	1 [14]	1 175	1 750	3 773	5 523	5 523
Module 6.1	Fee and levy	2 [14]	4 310	4 310	7 864	12 174	24 348
Module 6.2	Fee and levy	27 [14]	2 900	2 900	5 892	8 792	237 384
Module 6.3	Fee and levy	6 [14]	1 435	3 480	7 506	10 986	65 916
Module 7.1	Fee and levy	2 [14]	12 605	23 095	49 792	72 887	145 774
Module 7.2	Fee and levy	8 [14]	3 255	6 400	13 800	20 200	161 600
Module 7.3	Fee and levy	8 [14]	620	1 505	3 252	4 757	38 056
Module 8.1	Fee and levy	25 [14]	1 865	2 075	4 466	6 541	163 525
Module 8.2	Fee and levy	96 [14]	750	855	1 840	2 695	258 720
Module 8.3	Fee and levy	82 [14]	500	505	1 094	1 599	131 118

TABLE 19: COST RECOVERY ARRANGEMENTS 2014-15

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2014-15 COST RECOVERY VIA FEE ($)	2014-15 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[12] ($)	=A x B FORECAST TOTAL COST ($)
Module 9	Fee and levy	- [14]	1 175	1 175	-	1 175	-
Module 10.1	Levy	- [14]	Nil fee	-	-	-	-
Module 10.2	Levy	2 [14]	Nil fee	-	-	-	-
Module 10.3	Levy	2 [14]	Nil fee	-	-	-	-
Module 11.1	Fee and levy	53 [14]	2 230	3 545	7 650	11 195	593 335
Module 11.2	Fee and levy	181 [14]	1 175	1 350	2 914	4 264	771 784
Module 11.3	Fee and levy	- [14]	620	755	1 629	2 384	-
Module 11.4	Fee and levy	674 [14]	160	660	1 429	2 089	1 407 986
Module 12	Fee and levy	265 [14]	170	400	865	1 265	335 225
GMP Audit Assessment Fee - Category 1 and Multi-Category 2-4	Fee	80	N/a	7 500	466	7 966	637 289
GMP Audit Assessment Fee - Single Category 2-4	Fee	55	N/a	5 000	311	5 311	292 091
GMP Audit Assessment Fee - Category 6	Fee	80	N/a	1 800	112	1 912	152 949
GMP Foreign Assessment Fee	Fee	470	N/a	1 000	62	1 062	499 209
GMP Licence Application Fee	Fee	23	N/a	900	56	956	21 986

TABLE 19: COST RECOVERY ARRANGEMENTS 2014-15

ITEM OR ACTIVITY	METHOD OF RECOVERY	A ESTIMATED VOLUME OF ITEMS (no.)	CURRENT FEE ($)	2014-15 COST RECOVERY VIA FEE ($)	2014-15 COST RECOVERY VIA LEVY ($)	B FORECAST COST PER ITEM OR ACTIVITY[12] ($)	=A x B FORECAST TOTAL COST ($)
GMP Supplement Audit Review Fee	Fee	2	N/a	1 800	112	1 912	3 824
Certificate of Export (no technical assessment)	Fee	295	125	125	52	177	52 215
Certificate of Export (requires technical assessment)	Fee	110	230	230	90	320	35 200
HGP Notification number application and renewal	Fee	361	305	305	0	304	99 408
Investigation and enforcement	Annual fee	N/a	N/a	3 608 426	0	3 608 426	3 608 426
Chemical Review and AERP	Levy	N/a	N/a	0	2 913 173	2 913 173	2 913 173
Other expenditure	Other income and levy	N/a	N/a	-	173 487	173 487	173 487
Re-registration and re-approval scheme	Fee and levy	100	N/a	700	11 607	12 307	1 230 734
Pre-application advice	Fee	700	N/a	350	-	350	245 000
Total cost of activities							**32 856 672**
Deficit funded by equity	Equity						- 748 017
Total income							**32 108 655**

3.10 Summary of fee changes 2013–14 and 2014–15

Table 20 provides a summary of the projected changes to fees.

TABLE 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16] FROM 1 JULY 2013 MIN 30% COST RECOVERY	FEES ($)[16] FROM 1 JULY 2014 MIN 35% COST RECOVERY	FEES ($)[16] FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
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[17]	15 months	53 745	72 100	84 115	96 135
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

15 Legislative timeframes will change as a result of Better Regulation Reforms for applications received after 1 July 2013. To calculate the assessment period for modular applications, add the longest assessment period for items 2–10 to the relevant item 11 assessment period.

16 To calculate the fee for modular applications, total the modular fees for all items.

17 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 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16] FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
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[18]	15 months	34 925	48 465	56 545	64 620
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	27 505	32 090	36 675
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[19]	5 months	3 630	3 655	4 260	4 870
Category 6	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) the product is closely similar to a registered product; and (b) efficacy and safety data is **not** required to demonstrate the similarity of the product to the registered product; and (c) chemistry and manufacture data is required.	5 months	2 470	3 220	3 755	4 290

18 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.

19 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 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16]		
				FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
Category 7	Application for registration of a chemical product containing approved active constituent/s and approval of the product label if: (a) the product is closely similar to a registered chemical product; and (b) efficacy and safety data is **not** required to demonstrate the similarity of the product to the registered product; and (c) chemistry and manufacture data is **not** required.	3 months	660	1 315	1 535	1 755
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	1 250	1 455	1 665
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	1 195	1 395	1 595
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	21 460	25 035	28 610
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	875	1 020	1 170

TABLE 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16]		
				FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
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 13A	Application to change a relevant particular of an approval or registration where the relevant particular is set out in a legislative instrument made for section 26A of the Code.	2 months	385	385	385	385
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
APPLICATION FOR APPROVAL OF AN ACTIVE CONSTITUENT						
Category 15	Application for approval of an active constituent requiring a full assessment.	12 months	25 775	25 775	26 730	30 550
Category 16	Application for approval of an active constituent requiring a toxicological assessment other than as described in Category 15.	8 months	4 430	14 105	16 455	18 805
Category 17	Application for approval of an active constituent other than as described in Categories 15 or 16.	5 months	1 580	2 365	2 760	3 155
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	1 850	2 155	2 465
APPLICATION FOR A PERMIT						
Category 19	Application for a permit to possess or supply, other than for use in Australia, 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	350	350

TABLE 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16]		
				FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
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	350	350
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 3period	350	350	350	350
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 emergency use.	N/a	Nil fee	Nil fee	Nil fee	Nil fee
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
OTHER APPLICATIONS						
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 protocol 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	The modular assessment fee
Category 26	Re-registration and re-approval fee	N/a	N/a	N/a	700	700

TABLE 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16] FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
MODULAR FEES[20]						
Module 1	Screening		505	535	620	710
Module 2.1	Chemistry—Level 1	12 months	3 255	6 915	8 065	9 220
Module 2.2	Chemistry—Level 2	8 months	2 230	2 305	2 690	3 075
Module 2.3	Chemistry—Level 3	5 months	1 030	1 185	1 380	1 580
Module 2.4	Chemistry—Level 4	3 months	200	570	665	760
Module 3.1	Toxicology—Level 1	12 months	19 490	20 940	24 430	27 920
Module 3.2	Toxicology—Level 2	8 months	14 620	14 620	14 620	15 795
Module 3.3	Toxicology—Level 3	4 months	2 900	3 035	3 540	4 050
Module 4	Toxicology—*Scheduling*	12 months	3 720	2 435	2 435	2 435
Module 5.1	Residues—Level 1	12 months	5 595	13 630	15 900	18 170
Module 5.2	Residues—Level 2 (Registration only)	6 months	4 765	7 895	9 210	10 525
Module 5.3	Residues—Level 3 (Permit only)	6 months	2 490	6 150	7 175	8 200
Module 5.4	Residues—Level 4 (Registration only)	3 months	2 230	5 600	6 535	7 465
Module 5.5	Residues—Level 5 (Permit only)	3 months	1 175	1 500	1 750	2 000
Module 6.1	OH&S—Level 1	12 months	4 310	4 310	4 310	4 410

[20] The APVMA intends to introduce a new level for all technical modules to accommodate Global Joint Reviews. The fee will be equivalent to the Level 1 fee for the particular module.

TABLE 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16]		
				FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
Module 6.2	OH&S—Level 2	6 months	2 900	2 900	2 900	3 185
Module 6.3	OH&S—Level 3	4 months	1 435	2 985	3 480	3 980
Module 7.1	Environment—Level 1	12 months	12 605	19 795	23 095	26 390
Module 7.2	Environment—Level 2	6 months	3 255	5 485	6 400	7 315
Module 7.3	Environment—Level 3	4 months	620	1 290	1 505	1 720
Module 8.1	Efficacy and Safety—Level 1	5 months	1 865	1 865	2 075	2 370
Module 8.2	Efficacy and Safety—Level 2	4 months	750	750	855	975
Module 8.3	Efficacy and Safety—Level 3	3 months	500	500	505	580
Module 9	Non-food Trade	5 months	1 175	1 175	1 175	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	*Any other assessment*	6 months	Nil fee	Nil fee	Nil fee	Nil fee
Module 11.1	Finalise—Type 1	3 months	2 230	3 040	3 545	4 055
Module 11.2	Finalise—Type 2 (Registration only)	2 months	1 175	1 175	1 350	1 545
Module 11.3	Finalise—Type 3 (Permit only)	2 months	620	645	755	865
Module 11.4	Finalise—Type 4	2 months	160	570	660	755
Module 12	Data Protection		170	345	400	460
OTHER FEES & CHARGES						
Annual fee	Agricultural and Veterinary products	N/a	430	430	430	430

TABLE 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16]		
				FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
HGP application/ renewal fee		N/a	305	305	305	305
Certificate of Export	Requires technical assessment	N/a	230	230	230	230
Certificate of Export	No technical assessment	N/a	125	125	125	125
Database information		N/a	90/hr	95/hr	95/hr	95/hr
Electronic conversion of hard copy applications		N/a	N/a	90/hr	90/hr	90/hr
Advice		N/a	N/a	350	350	350
Advice (subsequent)[21]		N/a	N/a	175	175	175
GMP Audit Assessment Fee -- Category 1 and Multi-Category 2-4		N/a	N/a	7 500	7 500	7 500

[21] Per person per hour

TABLE 20: TABLE OF FEES AND ASSESSMENT PERIODS

ITEM	DESCRIPTION OF APPLICATION	CURRENT PERIOD[15]	CURRENT FEE ($)	FEES ($)[16]		
				FROM 1 JULY 2013 MIN 30% COST RECOVERY	FROM 1 JULY 2014 MIN 35% COST RECOVERY	FROM 1 JANUARY 2015 MIN 40% COST RECOVERY
GMP Audit Assessment Fee – Single Category 2–4		N/a	N/a	5 000	5 000	5 000
GMP Audit Assessment Fee —Category 6		N/a	N/a	1 800	1 800	1 800
GMP Foreign Audit Assessment Fee		N/a	N/a	1 000	1 000	1 000
GMP Licence Application Fee		N/a	N/a	900	900	900
GMP Supplemental Audit Review Fee		N/a	N/a	1 800	1 800	1 800

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 risks arising from the APVMA's activities and the effectiveness of systems that control these risks.

4.2 External accountability structures

The APVMA is subject to the same financial reporting requirements as other FMA Act 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 also subject to 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 three-month operating cost [the financial reserve]) and the repayment of any specific funds in future years.

Following implementation of revised cost recovery arrangements, the APVMA will monitor the ongoing effectiveness of the cost recovery arrangements as set out in Table 20.

TABLE 21: ONGOING MONITORING MECHANISMS FOR THE REVISED COST RECOVERY ARRANGEMENTS

MECHANISM	HOW	PURPOSE
Stakeholder consultation	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. 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. Through CEO meetings with major industry and community groups. Through the DAFF First-principles Review.	Obtain feedback to allow the APVMA to adapt its approach to cost recovery in response to changing circumstances. Reduce the impact of major reviews of cost recovery arrangements by allowing minor issues to be addressed as they arise. Report on the alignment of costs and revenue (over and under recovery) for pre- and post-market activities.
Cost recovery performance management arrangements	Align the cost recovery arrangements with the operational plan and a performance improvement strategy. Industry will be consulted during this process. Continue to utilise the annual report to demonstrate performance against the annual operational plan. Through the DAFF First-principles Review.	Enhance transparency of APVMA performance and reporting processes.
Financial modelling and policy framework	Test different cost scenarios and examine the net impact using ABC data and industry forecasts. Through the DAFF First-principles Review.	Ensure fees and charges are aligned with product costs and the APVMA's financial strategy is achieved. Ensure the overall cost recovery framework is structured appropriately.

4.4 Periodic review

Whilst reviews of cost recovery arrangements are only required to be undertaken every five years, DAFF in consultation with stakeholders will complete a First-principles review of the APVMA's 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 reforms to be fully implemented and flow through to activity levels 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). 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 2015 CRIS will also allow any changes to the cost recovery framework flowing from the First-principles Review of the APVMA's cost recovery arrangements to be adopted. The First-principles Review aims to examine and recommend options to strengthen the financial sustainability, transparency and accountability of the APVMA's cost recovery arrangements. Any changes to the APVMA's cost recovery arrangements as a result of the First-principles Review are subject to the Government's consideration and approval.

5 STAKEHOLDER CONSULTATION

In December 2011, the APVMA published a discussion paper that proposed interim cost recovery arrangements for the APVMA to cover the period 2012–15. A total of 14 submissions were received from industry organisations and individuals on the discussion paper.

Following consultation with a number of veterinary medicines industry groups an alternate proposal for the recovery of costs associated with the assessment of compliance with GMP was developed. The revised proposal was outlined in a supplementary discussion paper on cost recovery of compliance with GMP that was published in May 2012.

The APVMA has given careful consideration to the issues and concerns raised by stakeholders in submissions on both discussion papers.

Feedback on the discussion papers highlighted some legitimate concerns and the APVMA has decided not to proceed with some proposals. Other proposals have been revised following additional industry consultation. The decision to not proceed with a number of proposals is taken in the context of the upcoming First-principles Review, where all aspects of the APVMA's fees and charges will be examined.

Feedback from stakeholders in this report has been grouped into major themes, with examples from submissions included, followed by the APVMA's response. Full submissions to the discussion paper are available on the APVMA website.

5.1 Consultation results on discussion papers

Proposal to introduce indexation of fees

The December 2011 discussion paper proposed that indexation should be applied to application fees to ensure they remain at the 40 per cent target recovery rate.

Several stakeholders expressed concern relating to the proposal to introduce indexation on application fees, particularly before the First-Principles Review is completed.

In view of concerns raised in submissions, indexation of fees will not be introduced as part of the interim cost recovery arrangements outlined in this CRIS. Rather, indexation of fees will now be considered as part of the First-principles Review.

Proposal to increase the annual fee to include post-market activities

The December 2011 discussion paper proposed that the annual fee be increased to recover the costs of various post-market activities, such as the Adverse Experience Performance Program (AERP), chemical review and other post-market activities.

Several stakeholders expressed concern at this proposal. A number argued that these activities should be funded by the tax payer.

In view of concerns raised in submissions, the proposed changes to the annual fee will not be implemented as part of the interim cost recovery arrangements described in this CRIS.

Proposal to restore application fees to 40% cost recovery

The December 2011 discussion paper proposed that application fees be restored to the target 40 per cent cost recovery target with the remaining costs funded from the levy.

Submissions broadly supported restoring the cost recovery level on application fees to 40 per cent.

The APVMA will proceed with the restoration of the 40 per cent target for application fees but will spread the increase over an extra year (from two to two and a half years) to reduce the impact of the increase on applicants.

Proposal to recover 100% of the cost of Category 17 (generic actives)

The December 2011 discussion paper proposed to recover 100 per cent of the cost of processing Category 17 applications (approval of generic actives).

Several stakeholders expressed concern at this proposal. In view of the concern raised, the proposal to increase cost recovery for Category 17 will now be considered as part of the First-Principles Review and not introduced as part of this CRIS.

Proposal to recover the full costs of assessment of compliance with Good Manufacturing Practice

The December 2011 discussion paper proposed ways to establish more equitable cost recovery arrangements for assessment of compliance with GMP for veterinary medicines, whereby scheme participants pay for the cost of the activity.

Some industry stakeholders raised concerns about the proposed arrangements.

The APVMA worked with industry groups to develop an alternate proposal and this was outlined in the May 2012 discussion paper on cost recovery of assessment of compliance with GMP. Industry feedback on the revised proposal was very positive.

This CRIS documents the final cost recovery arrangements as outlined in the May 2012 discussion paper.

Proposal to introduce a fee rebate

The December 2011 cost recovery discussion paper proposed new arrangements to automatically refund to applicants 10 per cent of their original application fee if the application is not finalised within the specified statutory timeframe.

Feedback on the proposal to introduce a fee rebate was generally not supported. In view of the concerns raised by stakeholders, the APVMA will not proceed with the proposal to introduce a fee rebate.

Proposal to introduce a fee for pre-application advice fee

This proposal flowed directly from the Australian Government's Better Regulation reform agenda.

Stakeholders either supported the proposal or were neutral on it.

This CRIS documents the new fee for pre-application advice and a system of rebates for subsequent applications relating to the advice given.

Proposal to introduce a new fee for re-registration and re-approval applications

The APVMA's December 2011 Cost Recovery Discussion Paper proposed a new application fee to partly recover the cost of the re-registration and re-approval scheme (previously called 'Continuation'). During the consultation period for the cost recovery discussion paper, a number of stakeholders indicated they did not support the re-registration and re-approval scheme (and thus the associated fee).

However, the re-registration and re-approval scheme is Australian Government policy and stakeholders were not being asked to comment on it as such, just the fees associated with its operation. The APVMA must now make arrangements for the cost recovery for this new activity. Therefore, this CRIS documents a new application fee for applications for re-registration and re-approval.

Proposal to maintain the approach for minor use permits

The December 2011 Discussion Paper proposed to retain the 2005 approach of a $350 fee for Minor Use permits (Categories 19-21) where the balance of costs are recovered through the levy on wholesale sales.

This proposal was widely supported in submissions.

The APVMA will maintain the current approach to cost recovery for minor use permits.

Proposal to increase compliance and enforcement resourcing

The December 2011 Discussion Paper proposed to increase the APVMA's compliance and enforcement resource base to allow a more modern, graduated compliance system to be put in place. The paper argued that additional resources are required to fully utilise the range of new compliance enforcement tools flowing from the Better Regulation reforms. The increased resources will allow the full suite of compliance tools to be utilised while retaining the ability to respond to instances of major non-compliance. During consultation on the discussion paper no submissions objected to the proposal.

The APVMA will increase compliance and enforcement resourcing with the addition of five additional compliance staff.

6 CERTIFICATION

I certify that this CRIS complies with the Australian Government Cost Recovery Guidelines.

Dr Eva Bennet-Jenkins
Chief Executive Officer, APVMA

25 October 2012

APPENDICES

APPENDIX A: APVMA'S COST RECOVERY MODEL

Fee setting 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

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

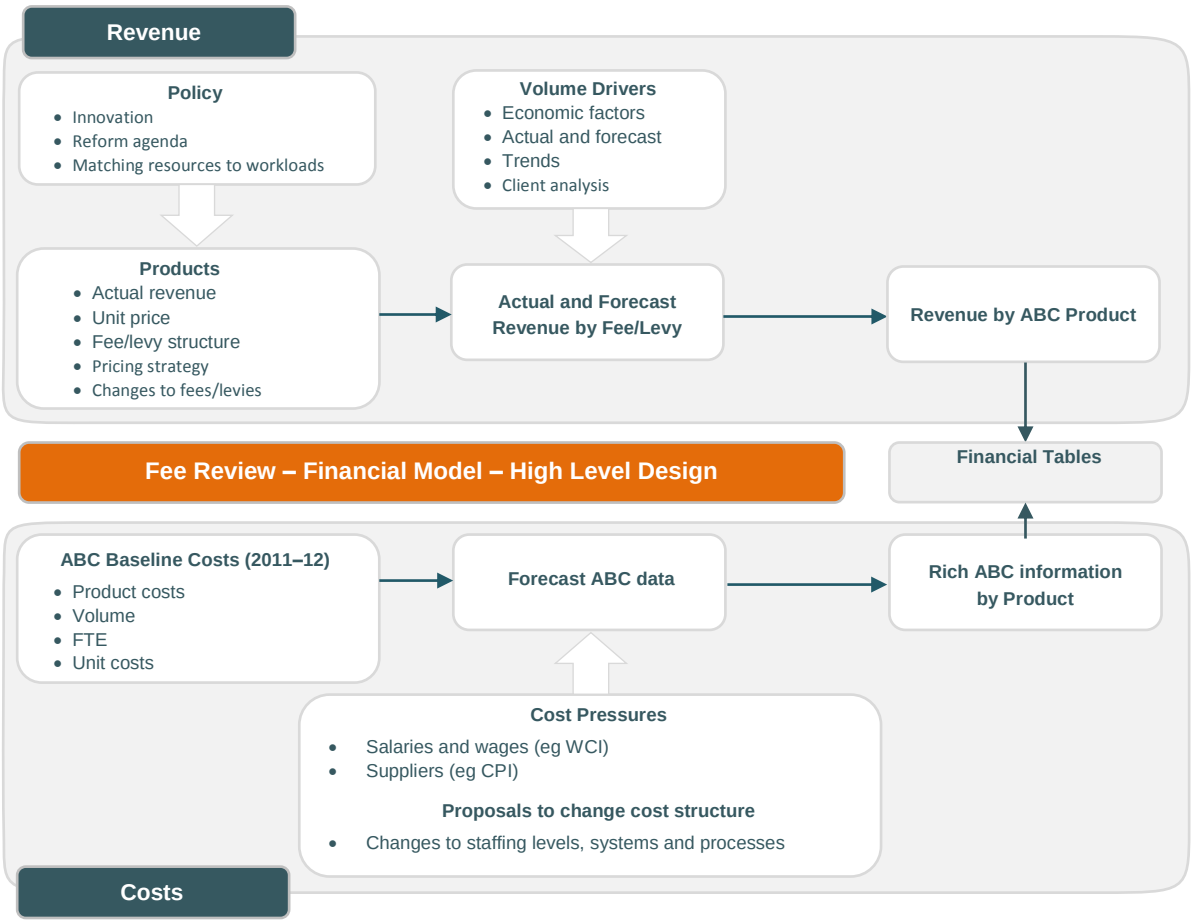
The principal driver used in the ABC study is the percentage of staff time taken (by level) to perform each activity, which has been determined through staff effort surveys. Throughout the staff consultation phase, and later through the development of surveys, ten sections (Pesticides Registration, Pesticides 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 costs.

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.

FIGURE 2: 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 2013–14 to finance additional Compliance and Enforcement staff
- forecast annual product sales for each product type increasing at 2.5 per cent
- forecast annual product registration applications: 0 per cent growth
- number of registered products: 2.5 per cent growth each year
- target recovery for product registration costs: at least 30 per cent from 1 July 2013, 35 per cent from 1 July 2014 and 40 per cent from 1 January 2015
- repayment of a total 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 expected levels.

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

TABLE 22: SECTION CONTRIBUTION TO THE COST OF APPLICATION CATEGORIES

SECTION	COST ($) OF CATEGORIES (2011-12)[22]								
	1[23]	3	4	5	6	7	8	9	11
Pesticide & Veterinary Registrations	11 484	11 484	11 484	5 210	5 210	2 437	2 323	2 237	11 484
Pesticide & Veterinary Residues	45 426	45 426	26 309	-	-	324	324	324	26 309
Pesticide & Veterinary Chemistry	23 044	3 948	3 948	3 948	3 948	-	-	-	-
AME	1 570	1 570	1 570	1 570	1 570	1 626	1 514	1 430	1 570
SAS	158 809	99 128	48 373	1 448	-	-	-	-	32 167
Total[24]	**240 333**	**161 556**	**91 684**	**12 176**	**10 728**	**4 387**	**4 161**	**3 991**	**71 530**

TABLE 23: SECTION CONTRIBUTION TO THE COST OF APPLICATION CATEGORIES (CONTINUED)

SECTION	COST ($) OF CATEGORIES (2011-12)[25]									
	12	13	15	16	17	18	19	20	21	22
Pesticide & Veterinary Registrations	2 427	3 948	1 146	1 146	1 146	-	1 499	1 499	1 499	1 499
Pesticide & Veterinary Residues	-	-	-	-	-	-	-	-	-	-
Pesticide & Veterinary Chemistry	-	-	29 659	29 659	6 738	6 161	-	-	-	-
AME	493	493	-	-	-	-	1 203	1 203	1 203	1 203
SAS	-	-	45 570	16 206	-	-	-	-	-	-
Total[51]	**2 920**	**4 441**	**76 375**	**47 011**	**7 884**	**6 161**	**2 702**	**2 702**	**2 702**	**2 702**

[22] Categories 2, 10 & 14 do not appear as they are modular categories.

[23] Categories 1,3 and 4 costs are the sum of the relevant fixed module costs

[24] Total cost for category, where relevant, takes average cost of Pesticides Residues and Veterinary Residues and average cost of Pesticides Registration and Veterinary Registration.

[25] Categories 14 and 23–25 do not appear as they are modular categories.

TABLE 24: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST ($) OF MODULES (2011-12)								
	1	2.1	2.2	2.3	2.4	3.1	3.2	3.3	4
Pesticide & Veterinary Registrations	1 282	-	-	-	-	-	-	-	-
Pesticide & Veterinary Residues	-	-	-	-	-	-	-	-	-
Pesticide & Veterinary Chemistry	-	23 044	7 687	3 948	1 902	-	-	-	-
AME	493	-	-	-	-	-	-	-	-
SAS	-	-	-	-	-	69 800	10 119	10 119	6 087
Total	**1 775**	**23 044**	**7 687**	**3 948**	**1 902**	**69 800**	**10 119**	**10 119**	**6 087**

TABLE 25: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST ($) OF MODULES (2011-12)							
	5.1	5.2	5.3	5.4	5.5	6.1	6.2	6.3
Pesticide & Veterinary Registrations	-	-	-	-	-	-	-	-
Pesticide & Veterinary Residues	45 426	26 309	20 499	18 667	5 000	-	-	-
Pesticide & Veterinary Chemistry	-	-	-	-	-	-	-	-
AME	-	-	-	-	-	-	-	-
SAS	-	-	-	-	-	11 020	7 960	9 945
Total	**45 426**	**26 309**	**20 499**	**18 667**	**5 000**	**11 020**	**7 960**	**9 945**

TABLE 26: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST ($) OF MODULES (2011-12)						
	7.1	7.2	7.3	8.1	8.2	8.3	9
Pesticide & Veterinary Registrations	-	-	-	-	-	-	-
Pesticide & Veterinary Residues	-	-	-	-	-	-	-
Chemistry	-	-	-	-	-	-	-
AME	-	-	-	-	-	-	-
SAS	65 979	18 285	4 306	5 922	2 439	1 448	-
Total	**65 979**	**18 285**	**4 306**	**5 922**	**2 439**	**1 448**	**-**

TABLE 27: SECTION CONTRIBUTION TO THE COST OF APPLICATION MODULES (CONTINUED)

SECTION	COST ($) OF MODULES (2011-12)							
	10.1	10.2	10.3	11.1	11.2	11.3	11.4	12
Pesticide & Veterinary Registrations	-	-	-	9 057	2 783	1 284	955	1 146
Pesticide & Veterinary Residues	-	-	-	-	-	-	-	-
Chemistry	-	-	-	-	-	-	-	-
AME	-	-	-	1 077	1 077	874	937	-
SAS	-	-	-	-	-	-	-	-
Total	**-**	**-**	**-**	**10 134**	**3 860**	**2 158**	**1 892**	**1 146**

APPENDIX C: IMPACT OF CHANGES ON COMPANIES OF DIFFERENT SIZES

TABLE 28: COMPARISON OF FEES PAID BY A TYPICAL LARGE COMPANY FROM 2012-13 TO 2014-15

	2012-13	2013-14		2014-15	
	CURRENT FEES	CURRENT FEES	NEW FEES	CURRENT FEES	NEW FEES
LEVY:					
Number of low selling products	*70*	*72*	*72*	*74*	*74*
Average sales per product ($)	*300 000*	*307 500*	*307 500*	*315 188*	*315 188*
Levy on low selling products ($)	168,000	177,120	154,980	186,591	146,941
Number of medium selling products	*34*	*35*	*35*	*36*	*36*
Average sales per product ($)	*2 000 000*	*2 050 000*	*2 050 000*	*2 101 250*	*2 101 250*
Levy on medium selling products ($)	425,000	445,375	392,000	466,403	365,558
Number of high selling products	*3*	*3*	*3*	*3*	*3*
Average sales per product ($)	*6 000 000*	*6 150 000*	*6 150 000*	*6 303 750*	*6 303 750*
Levy on high selling products ($)	87,000	88,350	78,488	89,734	70,678
Total levies paid ($)	**680,000**	**710,845**	**625,468**	**742,727**	**583,177**
ANNUAL FEE:					
Number of products renewed	*107*	*110*	*110*	*113*	*113*
Total annual fees paid ($)	**46 010**	**47 300**	**47 300**	**48 590**	**48 590**
GMP FEES:					
1 GMP Assessment Fee– Category 2-4 ($)	-	-	5 000		5 000
2 GMP Foreign Assessment Fees ($)	-	-	2 000		2 000
Total GMP fees paid ($)	**-**	**-**	**7 000**	**-**	**7 000**
APPLICATION FEES:					
1 Category 4 application lodged ($)	23 330	23 330	27 505	23 330	32 090
4 Category 7 applications lodged ($)	2 640	2 640	5 260	2 640	6 140
5 Category 8 applications lodged ($)	2 975	2 975	6 250	2 975	7 275
21 Category 12 applications lodged ($)	12 915	12 915	18 375	12 915	21 420
Total application fees paid ($)	**41 860**	**41 860**	**57 390**	**41 860**	**66 925**
RE-REGISTRATION FEES:					
10 x products requiring re-registration ($)	**N/a**	**N/a**	**N/a**	**-**	**7 000**
Overall fees and levies paid ($)	**767 870**	**800 005**	**737 158**	**833 177**	**712 692**

TABLE 29: COMPARISON OF FEES PAID BY A TYPICAL MEDIUM COMPANY FROM 2012-13 TO 2014-15

	2012-13	2013-14		2014-15	
	CURRENT FEES	CURRENT FEES	NEW FEES	CURRENT FEES	NEW FEES
LEVY:					
Number of low selling products	*41*	*42*	*42*	*43*	*43*
Average sales per product ($)	*250 000*	*256 250*	*256 250*	*262 656*	*262 656*
Levy on low selling products ($)	82,000	86,100	75,338	90,354	71,154
Number of medium selling products	*7*	*7*	*7*	*7*	*7*
Average sales per product ($)	*2 000 000*	*2 050 000*	*2 050 000*	*2 101 250*	*2 101 250*
Levy on medium selling products ($)	87,500	89,075	78,400	90,689	71,081
Total levies paid ($)	**169,500**	**175,175**	**153,738**	**181,043**	**142,235**
ANNUAL FEE:					
Number of products renewed	*48*	*49*	*49*	*50*	*50*
Total annual fees paid ($)	**20 640**	**21 070**	**21 070**	**21 500**	**21 500**
APPLICATION FEES:					
4 Category 7 applications lodged ($)	1 320	1 320	2 630	1 320	3 070
5 Category 8 applications lodged ($)	1 190	1 190	2 500	1 190	2 910
21 Category 12 applications lodged ($)	4 920	4 920	7 000	4 920	8 160
Total application fees paid ($)	**7 430**	**7 430**	**12 130**	**7 430**	**14 140**
RE-REGISTRATION FEES:					
5 products requiring re-registration ($)	**N/a**	**N/a**	**N/a**	**-**	**3 500**
Overall fees and levies paid ($)	**197 570**	**203 675**	**186 938**	**209 973**	**181 375**

TABLE 30: COMPARISON OF FEES PAID BY A TYPICAL SMALL COMPANY FROM 2012-13 TO 2014-15

	2012-13	2013-14		2014-15	
	CURRENT FEES	CURRENT FEES	NEW FEES	CURRENT FEES	NEW FEES
LEVY:					
Number of low selling products	*7*	*7*	*7*	*7*	*7*
Average sales per product ($)	*175 000*	*179 375*	*179 375*	*183 859*	*183 859*
Total levies paid ($)	**9 800**	**10 045**	**8 789**	**10 296**	**8 108**
ANNUAL FEE:					
Number of products renewed	*7*	*7*	*7*	*7*	*7*
Total annual fees paid ($)	**3 010**	**3 010**	**3 010**	**3 010**	**3 010**
APPLICATION FEES:					
1 Category 7 applications lodged ($)	660	660	1 315	660	1 535
2 Category 12 applications lodged ($)	1 230	1 230	1 750	1 230	2 040
Total application fees paid ($)	**1 890**	**1 890**	**3 065**	**1 890**	**3 575**
RE-REGISTRATION FEES:					
1 product requiring re-registration ($)	**N/a**	**N/a**	**N/a**	**-**	**700**
Overall fees and levies paid ($)	**14 700**	**14 945**	**14 864**	**15 196**	**15 393**

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 *Agricultural and Veterinary Chemicals Code Act 1994*
AME	Application Management and Enquiries
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
CAC Act	*Commonwealth Authorities and Companies Act 1997*
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: • fees for goods and services • 'cost recovery' taxes (primarily levies, but also some excises and customs duties).

APVMA's 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.
CRIS	Cost Recovery Impact Statement. A statement documenting compliance with the cost recovery policy.
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
FMA Act	*Financial Management and Accountability Act 1997*
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
Information activities	Activities involved in collecting, compiling and disseminating information or any other activity of a non-regulatory nature
MLS	Manufacturers' Licensing Scheme
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.
Reform Agenda	Better Regulation of Agricultural and Veterinary Chemicals reforms arising out of a Ministerial partnership between the Minister for Agriculture, Fisheries and Forestry and the Minister for Finance and Deregulation
Regulatory activities	Activities involved in administering regulations
Re-registration and re-approval scheme	A scheme introduced as part of the Better Regulation reforms for re-approval of active constituents and re-registration of agvet products. The scheme considers whether active constituent approvals and product registrations continue to satisfy the legislative tests that were applied to register products and approve active constituents.
RLC	Regulatory Liaison Committee
SAS	Scientific Assessment Services
Vet	Veterinary