Australian Government

Australian Pesticides and Veterinary Medicines Authority

(APVMA)

Cost Recovery Implementation Statement (CRIS)

Evaluation and registration of agvet chemicals and their regulation up to and including point of sale

1 July 2020 to 30 June 2022

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination of them. The Australian Government Charging Framework, which incorporates the Cost Recovery Guidelines (the CRGs)[1], sets out the framework under which government entities design, implement and review cost-recovered charging activities.

[1] The Cost Recovery Guidelines are available on the Department of Finance website.

Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

CONTENTS

1 INTRODUCTION 1

1.1 Purpose of the Cost Recovery Implementation Statement 1

1.2 Description of the regulatory charging activity 1

The agvet chemical industry 1

Functions and powers 1

Regulatory functions and services 3

2 POLICY AND STATUTORY AUTHORITY TO COST RECOVER 5

2.1 Government policy approval to recover the costs of the regulatory activity 5

Evaluation of applications for registration and approval 5

Pre-Application Assistance 5

Levies 5

Export Certificates and Consents to Import 5

GMP—manufacture licensing 5

2.2 Statutory authority to charge 6

3 COST RECOVERY MODEL 7

3.1 Cost recovery fee or levy 7

3.2 Outputs and business processes of the regulatory charging function 7

Registration and approvals 8

Monitoring ongoing compliance with regulations 11

Investigation and enforcement 11

Information activities 11

3.3 Costs of the regulatory charging activity 11

Costing methodology 11

Cost components 12

Registration and approvals 12

Monitoring ongoing compliance with regulations 14

Investigation and enforcement 15

Information activities 16

3.4 Design of regulatory charges 16

Need for change 16

Pricing 17

Fees to be maintained at current levels 17

The levy 18

Registration and approvals 19

Pre-Application Assistance (for products, active constituents and permits) 19

Consent to Import 19

Certificates of Export 19

Good Manufacturing Practice 20

Hormonal Growth Promotant Scheme 21

Product registration renewal fee 21

Implementation 21
Proposed fee changes from 1 July 2020 22
Proposed revised cost recovery arrangements from 1 July 2020 30

4 RISK ASSESSMENT 34
4.1 Risk mitigation 34

5 STAKEHOLDER ENGAGEMENT 35
5.1 Support for the agvet chemical regulatory framework 35
5.2 Consultation and implementation timeframes 36
5.3 Consideration of previous reviews 36
5.4 Efficiency of the APVMA 36
5.5 Public good 36
5.6 Other issues 36

6 RESPONSE OF THE APVMA TO STAKEHOLDER FEEDBACK 37

7 FINANCIAL ESTIMATES 39
7.1 Forecast operating results of cost recovery arrangements 39
7.2 APVMA's financial reserve 39

8 PERFORMANCE 40
8.1 Financial performance 40
8.2 Non-financial performance 41

9 KEY FORWARD DATES AND EVENTS 42

10 CRIS APPROVAL AND CHANGE REGISTER 43

GLOSSARY OF TERMS AND ABBREVIATIONS 46

LIST OF TABLES

Table 1: The APVMA's regulatory functions and services 7
Table 2: Application Items and cost recovery mechanisms 8
Table 3: Cost components of registration and approvals 13
Table 4: Cost components of Pre-Application Assistance (included in Table 3) 13
Table 5: Cost components of Certificates of Export 14
Table 6: Cost components of GMP compliance assessment 14
Table 7: Cost components of the HGP Scheme 15
Table 8: Cost components of the AERP and Chemical Review Program 15
Table 9: Cost components of investigation and enforcement 16
Table 10: Registration renewal fee increases 17
Table 11: Levy rates 18
Table 12: Pre-Application Assistance—rebates payable 19
Table 13: Certificate of Export fees and charges from 1 July 2020 20
Table 14: GMP fees and charges from 1 July 2020 20
Table 15: Hormonal Growth Promotant fees and charges from 1 July 2020 21
Table 16: Estimated registration renewal fee revenue 2020–21 to 2021–22 21
Table 17: Proposed revised fees effective from 1 July 2020 22
Table 18: Proposed Item cost recovery arrangements from 2020–21 (full year) 30
Table 19: Proposed other cost recovery arrangements from FY2020–21 33
Table 20: Forecast operating results FY2020–21 to FY2021-22 39
Table 21: Actual operating results FY2014–15 to FY2018–19 40
Table 22: CRIS approval and change register 43

1 INTRODUCTION

1.1 Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) outlines how the Australian Pesticides and Veterinary Medicines Authority (APVMA) proposes to implement revised cost recovery arrangements. The arrangements relate to the agency fulfilling its statutory function to ensure that agricultural chemicals and veterinary medicines sold within Australia are safe and effective and do not unduly prejudice trade.

The CRIS provides financial forecasts for the reporting period FY2020–21 to FY2021–22. This CRIS represents the outcomes of stakeholder consultations on the draft CRIS conducted in 2019. This CRIS also sets out the Government's commitment to ensure cost recovery revenue will be allocated to efficiently and effectively deliver demand-driven regulatory activities.

The CRIS reflects the outcome of detailed activity based cost and regulatory services price modelling and stakeholder consultations to date associated with the need to fully recover the costs of regulatory services provided to industry and consumers. Existing fees and charges have not been increased since 1 January 2015. There is also a need to concurrently replenish the APVMA financial reserve which has been significantly depleted over the intervening period as a consequence of no real price increases since 1 January 2015. The proposed new fees reflect the revised activity based full costs of the regulatory function as well as improved processes and efficiency resulting from improvements to registration and evaluation standard operating procedures over recent years. The implementation of a new and revised fee structure is crucial to ensuring the full cost recovery of all regulatory services the APVMA provides to industry.

1.2 Description of the regulatory charging activity

The agvet chemical industry

The agvet chemical industry is the primary beneficiary of the agvet regulatory process as without regulatory approval, industry cannot market their products for sale in Australia. Therefore, it is appropriate that industry bears the full efficient costs of the regulatory function delivered by the APVMA.

The wholesale value of veterinary product sales tends to be relatively stable, whereas the wholesale value of agricultural product sales tends to be 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 as it is based on the immediate past year product sales revenue.

While the Australian community and consumers of agvet products benefit from chemicals being available, ultimately it is the agvet chemical industry that is the primary beneficiary of the agvet regulatory process as without regulatory approval, industry cannot market their products for sale in Australia.

Functions and powers

The APVMA operates under an intergovernmental agreement between the Australian Government and all states and territories. Under this agreement, APVMA's regulatory responsibilities extend from registration and

manufacturing through to the point of sale. The states and territories are responsible for regulating agvet chemicals after they are sold.

The key functions of the APVMA, which are set out in s.7 of the Administration Act, are:

a) to assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, chemical products and labels for containers for chemical products

b) to provide information to the Governments and authorities of the Commonwealth, the states and the participating territories about approved active constituents for proposed or existing chemical products, registered chemical products, reserved chemical products and approved labels for containers for chemical products and to co-operate with those Governments and authorities on matters relating to the management and control of chemical products

c) to keep records and statistics of approvals and registrations granted, and permits and licences issued, by it under the Agvet Codes

d) to evaluate the effects of the use of chemical products in the states and participating territories

e) to co-operate with Governments and authorities of the Commonwealth, the states and the participating territories for the purpose of facilitating a consistent approach to the assessment and control of chemicals

f) in co-operation with Governments and authorities of the Commonwealth, the states and the participating territories, to develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products in the states and participating territories

g) to collect, interpret, disseminate and publish information relating to chemical products and their use

h) to encourage and facilitate the application and use of results of evaluation and testing of chemical products

i) to exchange information relating to chemical products and their use with overseas and international bodies having functions similar to the APVMA's functions

j) when requested by the Minister, or on its own initiative, to report to or advise the Minister on any matter relating to chemical products or arising in the course of the performance of its functions

k) to encourage and facilitate the introduction of uniform national procedures for control of the use of chemical products

l) to fund, and co-operate in, a program designed to ensure that active constituents for proposed or existing chemical products, chemical products, and labels for containers for chemical products, comply with the Agvet Codes and the Agvet Regulations.

Under section 10 of the Administration Act, the Australian Government Minister responsible for administering agricultural chemicals and veterinary medicine legislation may direct the APVMA (in writing) concerning the performance of its powers under Australian, state or territory laws. The APVMA must comply with any such direction.

Regulatory functions and services

The APVMA's regulatory functions are summarised in the following paragraphs. More details of the regulatory services are at section 3.

A. Registrations and approvals

EVALUATION OF APPLICATIONS FOR REGISTRATION AND APPROVAL

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

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, and that it is effective. 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.

B. Monitoring ongoing compliance with regulations

EVALUATION OF APPLICATIONS FOR GOOD MANUFACTURING PRACTICE

Veterinary chemical products manufactured in Australia must be manufactured in premises which are Good Manufacturing Practice (GMP) compliant. This does not apply to agricultural chemical products.

GMP compliance is assessed for Australian manufacturers through the Manufacturing Quality and Licensing Scheme and for products manufactured overseas via the overseas GMP scheme.

This ensures that veterinary products are manufactured to an approved standard through a quality assurance scheme based on GMP.

HORMONAL GROWTH PROMOTANT SCHEME

The APVMA is responsible for controlling the supply of Hormonal Growth Promotants (HGPs) within the National HGP Control and Monitoring System managed by the Department of Agriculture, Water and the Environment. 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 notification to the APVMA and payment of relevant fees to the APVMA.

ADVERSE EXPERIENCE REPORTING PROGRAM

The Adverse Experience Reporting Program (AERP) is the main mechanism for the APVMA to receive and consider stakeholder and public feedback on adverse experiences relating to the use of agvet chemicals post-registration.

CHEMICAL REVIEW PROGRAM (RECONSIDERATION)

The Chemical Review Program reconsiders the registration of agvet chemicals where credible safety and/or efficacy concerns have been identified. Reviews may focus on one or more areas of concern including environmental safety, worker safety, public health, residues, trade, or product efficacy. The Program aims to ensure that chemicals approved for sale and use in Australia can continue to satisfy regulatory requirements.

C. Investigation and enforcement

The APVMA monitors 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 surveillance, and monitors chemical production in Australia.

D. Information activities

The APVMA provides information on agvet chemical regulatory arrangements through the APVMA website, corporate publications, industry consultation, and presentations and seminars. The APVMA also assists in the development of policy and undertakes parliamentary servicing functions, including attending Senate Estimates hearings, the provision of answers to Questions on Notice, and the provision of Ministerial briefings.

2 POLICY AND STATUTORY AUTHORITY TO COST RECOVER

2.1 Government policy approval to recover the costs of the regulatory activity

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, registration renewal fees 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 (Agvet Code Regulations) made under the A*gricultural 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.

Evaluation of applications for registration and approval

The Agvet Code Regulations sets out separate Items of applications. Application fees are either fixed or are determined by a 'modular' assessment fee structure based on the types and levels of assessment necessary.

Pre-Application Assistance

The APVMA has established fees for Pre-Application Assistance in a legislative instrument: the Agricultural and Veterinary Chemicals Code (Pre-application Assistance Fee) Instrument 2015.

Levies

The levies payable on the disposal 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.

Export Certificates and Consents to Import

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*.

The APVMA Consents to Import are also provided for in the Administration Act but there is no legislative authority for the APVMA to charge fees for these.

GMP—manufacture licensing

GMP Audit Assessment fees utilise subsection 164 (1) of the Agvet Code and relevant provisions of the Agvet Code Regulations.

The Licence Application Fee is directly attached to the application for a licence via paragraph 122(1) (c) of the Agvet Code.

2.2 Statutory authority to charge

The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act). The Administration Act sets out the APVMA's role to administer the National Registration Scheme for Agricultural and Veterinary Chemicals in partnership with state and territory governments, and the scheme's legislation.

Functions and powers are conferred on the APVMA by the Administration Act, the Agvet Code, the Agvet Code Regulations, and the Agvet Codes and Agvet Regulations of each state and participating territory.

The APVMA is a Corporate Commonwealth Entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).

3 COST RECOVERY MODEL

3.1 Cost recovery fee or levy

The Cost Recovery Guidelines provide that the characteristics of a government activity determine the type of cost recovery charge used. There are two types of cost recovery:

1. **cost recovery fees:** fees charged when a good, service or regulation (in certain circumstances) is provided directly to a specific individual or organisation
2. **cost recovery levies:** charges imposed when a good, service or regulation is provided to a group of individuals or organisations (eg an industry sector) rather than to a specific individual or organisation. A cost recovery levy is a tax and is imposed via a separate taxation Act. It differs from general taxation as it is 'earmarked' to fund activities provided to the group that pays the levy.

3.2 Outputs and business processes of the regulatory charging function

A summary of the APVMA's regulatory function and high level outputs is shown Table 1 below.

Table 1: The APVMA's regulatory functions and services

Functions		Outputs (services)
Pre-market regulation activities	Registration and approvals	Registration and approvals—evaluation of applications (including permits)
		Certificates of Export
		Consents to Import
		Pre Application Assistance
Post-market regulation activities	Monitoring ongoing compliance with regulations	Good Manufacturing Practice (GMP) compliance—evaluation of applications compliance
		Hormonal Growth Promotant Scheme
		Adverse Experience Reporting Program (AERP)
		Chemical Review
	Investigation and enforcement	Compliance and Enforcement
Information activities	Information activities	Website
		Corporate publications
		Presentations and seminars
		Informing policy

Details of APVMA's regulatory outputs and proposed cost recovery arrangements follow.

Registration and approvals

The Items and Modules listed in the current schedule of cost recoverable fees and charges have several levels of evaluation related to the complexity and duration of the assessments undertaken. This complexity underpins the pricing of the Items in the fee schedule. All Items and Modules have assessment periods (duration) attached to them.

Table 2: Application Items and cost recovery mechanisms

Type of application		Item	Cost recovery mechanism
Product applications	New product registrations	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 13A, 14	40% recovery through fees with the remaining costs funded by the levy.
	Variations to registered products	11, 12	
		13	No charge for this application Item. The cost of processing these applications is funded by the registration renewal fee.
		13A, 14	40% recovery through fees with the remaining costs funded by the levy.
Active applications		15, 16, 17, 18	
Permit applications		19, 20, 21	Fixed fee ($350) for these application Items with the remaining costs funded by the levy.
		22	No charge for this application Item. The cost of processing these applications is funded by the levy.
		23	40% recovery through fees with the remaining costs funded by the levy.
Other applications		24	
Technical Assessment		25	
Timeshift applications		27	
Ingredient determination		28	
Interchangeable constituent determination		29	

Items 1–14 (product applications)

Items 1–14 are applications seeking to register new products or for applications seeking variations to an existing product registration.

Items 15–18 (active constituent applications)

Items 15–18 are for approval of active constituents. Items 15 and 16 are for applications seeking the approval of a new active constituent, Item 17 is for existing active constituents and Item 18 is for variations to an approved active constituent.

Items 19–23 (permit applications)

Item 19 is for a permit to export an unregistered Agvet chemical product.

Item 20 is for applications seeking to extend (or renew) the duration of a previously issued permit.

Item 21 is for applications seeking a minor use permit. Minor use permits are issued for the use of an agvet chemical in small, emerging or niche industries where an insufficient economic return exists for a registrant to pursue product registration.

Item 22 is for applications seeking an emergency use permit 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.

Item 23 is for applications seeking a research permit to 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 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.

There is an exemption to permit application fees where the Australian, state or territory governments apply for a permit in support of their core business. Activities not considered to be fee exempt would include those activities where a profit is obtained 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.

Item 24 (approval or registration under section 10) and Item 25 (application for a technical assessment under Reg 8AS)

Item 24 and 25 applications are for any other assessment that is not covered by Items 1–23, or 27–29.

Item 27 (timeshift application)

A timeshift application provides for the staged submission of supporting data packages allowing commencement of longer assessments (such as toxicology and environment) while other supporting data packages (such as efficacy and crop safety) are being completed.

The application is assessed according to a project plan which is developed and agreed between the applicant and the APVMA.

Item 28 (ingredient determination)

These are technical assessments made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination.

Item 29 (interchangeable constituent determination)

Applications for an Interchangeable Constituent Determination (ICD) that allows specified non-active constituents (excipients) to be substituted by other specified excipients without assessment. These determinations can apply to a single chemical product, a range of chemical products or a class of chemical products.

Pre-Application Assistance (for registrations, approvals and permits)

Applicants are encouraged to seek Pre-Application Assistance (PAA) on the applications that they are preparing. Assistance provided may include selection of the correct Item for the application together with advice on the data requirements for an application.

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[2]. Consents to import are issued under limited circumstances, for example to veterinarians for the use of a product on animals under their care where no suitably registered product exists within Australia or where an APVMA Permit covers the supply or use of such a product.

No fee is charged for this service. The Consent to Import activity is funded via the registration renewal fee.

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.

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

Those who wish to obtain a Certificate of Export are charged a direct fee for this service with the residual cost to be recovered from the levy.

Monitoring ongoing compliance with regulations

Evaluation of applications for Good Manufacturing Practice

Good Manufacturing Practice (GMP) related costs are each recovered through a mixture of fees and levies.

Hormonal Growth Promotant Scheme

The Hormonal Growth Promotant (HGP) scheme is funded through a direct fee to users of the service.

Adverse Experience Reporting Program

The full cost of the Adverse Experience Reporting Program (AERP) is recovered through the registration renewal fee and the levy.

Chemical Review Program

The full cost of the Chemical Review Program is recovered through the registration renewal fee and the levy.

Investigation and enforcement

The full cost of investigation and enforcement is recovered through the registration renewal fee and the levy.

Information activities

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

3.3 Costs of the regulatory charging activity

Costing methodology

Standard Activity Based Costing (ABC) methodology was used to allocate expenses to activities and activity costs to outputs (services) using volume-based cost drivers. This method enables more informed analysis of the efficiency of outputs and business processes of the activity. The cost data for the assessment of products and their registration and subsequent management of the product register post market were estimated on the following bases:

- all regulatory activities delivered on a cost recovery basis were identified in consultation with regulatory management and staff
- corporate support activities undertaken were identified in consultation with relevant corporate management and staff

- staff salary and on costs were allocated to activities based on staff estimated effort (time) spent on activities at salary rates (at staff classification levels) as is recommended by the CRGs
- actual supplier costs
- corporate and other overhead costs were attributed to activities and outputs based on suitable and appropriate drivers, FTE being the common driver used
- application volume data used to derive unit prices were 2018–19 actuals.

Cost components

In line with the CRGs, the cost recovery model includes the following cost components:

- **direct costs:** allocation of direct costs is relatively straightforward. The direct costs included in the cost model are staff salaries (including on-costs for superannuation and leave) for those directly involved in the activity, and supplier costs (eg contractors, consultants, and legal)
- **indirect costs:** are those costs that cannot be easily linked or where tracking this outweighs the benefits. Indirect costs are allocated as overheads to the staff directly involved in performing the regulatory activities using the Department of Finance's approved costing methodology.

The tables below detail the total cost per service by direct and indirect components. The costs reported are based on the results of the activity based full costing of the regulatory service outputs of the entity.

Registration and approvals

Evaluation of applications for registration and approval

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 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 activity recovered by a tiered levy on the annual value of product sales.

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.

The FY2020–21 estimated total costs of registration and approvals outputs are shown in Table 3.

Table 3: Cost components of registration and approvals

Expense	Inclusions	Attribution	Annual cost ($)
Service: registration and approvals			
Employee expenses	Technical and administrative assessment costs	Direct Cost	14 016 490
Suppliers	Outsourced activities—scientific assessment services undertaken by external agencies	Direct Cost	2 504 378
Overheads		Indirect Cost	12 742 335
Other Activity Costs		Indirect/Direct Costs	
Total			**29 263 203**

Pre-Application Assistance (for products, active constituents and permits)

Pre-Application Assistance activities are included in the registration and approvals costs above, but are detailed separately below in Table 4.

Table 4: Cost components of Pre-Application Assistance (included in Table 3)

Expense	Inclusions	Attribution	Annual cost ($)
Service: Pre-Application Assistance			
Employee expenses	Technical and administrative assessment costs	Direct Cost	692 491
Suppliers	Outsourced activities	Direct Cost	-
Overheads		Indirect Cost	-
Other Activity Costs		Indirect/Direct Costs	-
Total			**692 491**

Note: Indirect overhead costs were not assigned to this service.

Certificates of Export

The FY2020–21 estimated costs for Certificates of Export are shown in Table 5.

Table 5: Cost components of Certificates of Export

Expense	Inclusions	Attribution	Annual cost ($)
Service: Certificates of Export			
Employee expenses	Assessment and administrative services	Direct Cost	32 337
Suppliers	Outsourced activities	Direct Cost	13 787
Overheads		Indirect Cost	24 965
Other Activity Costs		Indirect/Direct Costs	39 750
Total			**110 839**

Consents to Import

No fee is charged for this service. The Consent to Import activity is funded via the registration renewal fee.

Monitoring ongoing compliance with regulations

Evaluation of applications for Good Manufacturing Practice

The FY2020–21 estimated costs of the Good Manufacturing Practice (GMP) compliance assessment schemes are shown in Table 6.

Table 6: Cost components of GMP compliance assessment

Expense	Inclusions	Attribution	Annual cost ($)
Service: GMP compliance assessment schemes			
Employee expenses	Assessment of MLS licences and imported products for GMP compliance; and management of GMP auditing	Direct Cost	336 439
Suppliers	Outsourced activities	Direct Cost	143 849
Overheads		Indirect Cost	261 993
Other Activity Costs		Indirect/Direct Costs	438 859
Total			**1 181 140**

Hormonal Growth Promotant Scheme

The FY2020–21 estimated costs for the Hormonal Growth Promotant (HGP) Scheme are shown in Table 7.

Table 7: Cost components of the HGP Scheme

Expense	Inclusions	Attribution	Annual cost ($)
Service: HGP Scheme			
Employee expenses	Assessment of new licences, licence renewals, licence withdrawals and HGP audits (including investigations)	Direct Cost	38 458
Suppliers	Outsourced activities	Direct Cost	9 192
Overheads		Indirect Cost	16 841
Other Activity Costs		Indirect/Direct Costs	27 645
Total			**92 136**

Adverse Experience Reporting Program and Chemical Review Program

The costs of both programs are recovered through the registration renewal fee and the levy.

The FY2020–21 estimated costs for the Adverse Experience Reporting Program (AERP) and Chemical Review are shown in Table 8.

Table 8: Cost components of the AERP and Chemical Review Program

Expense	Inclusions	Attribution	Annual cost ($)
Service: AERP and Chemical Review			
Employee expenses	Review work, AERP	Direct Cost	1 507 177
Suppliers	Outsourced activities	Direct Cost	597 271
Overheads		Indirect Cost	1 439 462
Other Activity Costs		Indirect/Direct Costs	-
Total			**3 543 910**

Investigation and enforcement

Costs of investigation and enforcement activities are fully recovered through the registration renewal fee and the levy.

The FY2020–21 estimated costs for investigation and enforcement are shown in Table 9.

Table 9: Cost components of investigation and enforcement

Expense	Inclusions	Attribution	Annual cost ($)
Service: Investigation and enforcement			
Employee expenses	Non-compliance report processing, product recalls and investigations	Direct cost	1 196 966
Suppliers	Outsourced activities	Direct Cost	459 580
Overheads		Indirect cost	919 042
Other Activity Costs		Indirect/Direct Costs	-
Total			**2 575 588**

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 National Registration Scheme.

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

3.4 Design of regulatory charges

This section details the APVMA's proposed cost recovery arrangements to apply from 1 July 2020.

Need for change

An independent review of the APVMAs cost recovery arrangements was undertaken and the review report was delivered in October 2017[3]. The key finding of the review was that the costs of the APVMA's activities were not being covered by the current fee structure. The review further advised that there was an imbalance between revenue and expense which was forecast to grow without remedial action being taken.

Subsequent monitoring of its cost recovery performance enabled APVMA to identify issues with the cost recovery arrangements, including as follows:

- cost recovery for product evaluations have fallen below the target of 40 per cent recovery through upfront application fees. The recovery rate is currently averaging around 28.1 per cent with the remaining costs funded through the levy because the real activity based costs of product evaluation and regulation have not been reflected in the fee structure over recent years

[3] PricewaterhouseCoopers (PwC), Review of Cost Recovery Arrangement, October 2017, agriculture.gov.au/sites/default/files/sitecollectiondocuments/ag-food/agvet/apvma-cost-recovery-review-report.pdf.

- GMP compliance assessment costs have been under-recovered annually, with the difference funded through the levy.

Pricing

The results of the recent detailed Activity Based Costing of all the regulatory service outputs of the APVMA revealed that changes are needed across most, if not all, the current prices of applications.

Prices have been set based on achieving close to parity in increased revenue from registration renewal fees and product application fee sources each year. In order to achieve this, registration renewal fees will increase as follows in Table 10.

Table 10: Registration renewal fee increases

	Payable annually	Payable for 5 years in advance
FY2020–21	$550	$3 350
FY2021–22	$600	$3 650

Proposed application fee increases are currently capped at 72.5 per cent for FY2020–21 but will also need to increase annually as costs increase. Current expectations are that Item and Module fees will both need to be adjusted annually, with price increases to continue to be capped, to generate revenue from application fees close to equal the revenue expected from registration renewal fees. Note that there will be nil adjustments of any calculated price decreases to Modules and Items.

Fees to be maintained at current levels

Nil changes are proposed to other fees and charges not mentioned in this CRIS, and specifically the following:

- Item 13
- Item 13A
- Item 19
- Item 20
- Item 21
- Notifiable variations
- Item 22
- PAA and related rebates
- Consent to Import*
- Certificates of Export
- GMP Audit Assessment
- GMP Foreign Audit Assessment

- GMP Licence Application
- GMP Supplemental Audit Review
- AERP*
- Chemical Review Program*
- Compliance and enforcement*
- 8L, 8M and 8P.

* These activities are cost-recovered through the registration renewal fee and the levy.

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. The current levy tiers are as follows:

- levy tier 0: rate for annual product sales below $5000
- 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.

Current levy rates are shown in Table 11. No change is proposed to levy tiers (thresholds).

Table 11: Levy rates

Based on sales	Current
Levy tier 0 (annual product sales below $5 000)	0.00%
Levy tier 1 (annual product sales up to $1 000 000)	0.63%
Levy tier 2 (annual product sales between $1 000 001 and $5 000 000)	0.35%
Levy tier 3 (annual product sales greater than $5 000 000)	0.25%

Registration and approvals

This CRIS reflects changes to the APVMA's cost recovery arrangements to restore the original intent that 40 per cent of the costs of assessing applications should be recovered as an upfront application fee with the remaining costs funded by a levy on the annual value of sales.

Pre-Application Assistance (for products, active constituents and permits)

Fees are charged for advice relating to product registrations, active constituent approvals and permit applications.

Applicants are encouraged to seek Pre-Application Assistance on the applications that they are preparing to clarify data requirements etc. The full cost of the activity is partially recovered from the application fee and the bulk of the cost is recovered by levy. A rebate will continue to be provided if the applicant proceeds to lodge an application with the rebate varying according to the Item of the application, as set out in Table 12.

The rebate is provided in recognition that the Pre-Application Assistance 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 Items. Advice provided may include assistance with the selection of the correct Item 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 payable are shown in Table 12.

Table 12: Pre-Application Assistance—rebates payable

Item	Fee
1, 2, 15, 27	$1 400
3, 4, 11	$1 050
5, 6, 16, 17, 18	$700
7, 8, 9, 10, 10A 12, 14, 19, 20, 21, 23, 24	$350
13, 13A, 22, 25, 28, 29, re-registration and re-approval	**Nil**

Consent to Import

No fee is charged for this service. The Consent to Import activity is funded via the registration renewal fee.

Certificates of Export

The full cost of the activity is partially recovered from the applicant by fee and the residual cost is recovered by the levy.

Table 13: Certificate of Export fees and charges from 1 July 2020

Type	Item	Number	Fee ($)	Fee revenue ($)
Service: Certificate of Export fees and charges				
Australian Manufacturers	Certificate of Export (no technical assessment)	40	125	5 000
Australian Manufacturers	Certificate of Export (requires technical assessment)	40	230	9 200
Total				**14 200**

Good Manufacturing Practice

Costs for the Manufacturers' Licensing Scheme (MLS) have been under-recovered annually, with the difference funded through the levy.

Good Manufacturing Process (GMP) fees are shown in Table 14.

Table 14: GMP fees and charges from 1 July 2020

Type	Item	Forecast volume	Fee ($)	Fee revenue ($)
Service: GMP compliance assessment schemes—fees				
Australian Manufacturers	GMP Audit Assessment Fee—Item 1 (Single and Multi-Item 1) and Multi-Item 2–4	65	7 500	487 500
Australian Manufacturers	GMP Audit Assessment Fee—Single Item 2–4	40	5 000	200 000
Australian Manufacturers	GMP Audit Assessment Fee—Item 6 (Single-step manufacture)	65	1 800	117 000
Australian Importers/Registrants (per registrant/site)	GMP Foreign Audit Assessment Fee	360 registrant sites*	1 000	360 000
Activity: GMP compliance assessment schemes—licence application and various other administrative fees				
Australian Manufacturers	Licence Application Fee	10	900	9 000
Australian Manufacturers	Supplemental Audit Review Fee	2	1 800	3 600
Total				**1 177 100**

* 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).

Hormonal Growth Promotant Scheme

Part of the cost of the activity is recovered by a direct fee which will increase from $305 to $429 from 1 July 2020.

Table 15: Hormonal Growth Promotant fees and charges from 1 July 2020

Type	Item	Forecast volume	Fee ($)	Fee revenue ($)
Service: Hormonal Growth Promotant fees and charges				
Australian Manufacturers	HGP Notification number application and renewal	215	429	92 136
Total				**92 136**

Product registration renewal fee

The registration renewal fee is payable by 31 May each year to maintain a product on the register for the following financial year. The fee funds the APVMA's compliance activities, the cost of processing category 13 applications as well as Consents to Import, and the costs associated with maintaining the product register. This cost recovery approach will continue although a change will be made to the existing registration renewal fee increasing it to $550 for all products in FY2020–21. Stepped increases in the registration renewal fee are also proposed in the following year primarily to cover cost increases.

Estimated registration renewal fee revenue is shown in Table 16 below.

Table 16: Estimated registration renewal fee revenue 2020–21 to 2021–22

	2020–21	2021–22
Estimated number of registered products	12 150	12 150
Fee per registered product ($)	550	600
Total ($)	**6 682 500**	**7 290 000**

Implementation

The proposed revised fees and charges regime will commence from 1 July 2020 subject to amending legislation being passed before 30 June 2020.

Application fee changes will apply to any new applications submitted from 1 July 2020 and new fees for product registration renewals will also apply in full in FY2020–21.

Proposed fee changes from 1 July 2020

The following table provides a complete listing of the APVMA's proposed revised fees for 2020–21 to take effect from 1 July 2020.

Table 17: Proposed revised fees effective from 1 July 2020

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
Application for registration of a product containing a new active constituent/s and approval of the product label				
Item 1	Application for approval of new active constituent/s contained in a product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active/s and product.	18 months	96 135	116 501
Item 2	Application for approval of new active constituent/s contained in a product, registration of the associated chemical product and approval of the product label other than as described in Item 1.	Modular assessment period	Modular assessment fee	Modular assessment fee
Application for registration of a product containing approved active constituent/s and approval of the product label				
Item 3	Application for registration of a chemical 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 months	64 620	83 511
Item 4	Application for registration of a chemical 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) a full assessment of the product is required and there are no relevant maximum residue limits and poison classification is required.	18 months	36 675	44 644

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
Item 5	a) Registration of a chemical product containing an approved active constituent and approval of the product label; or b) Registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or c) Registration of a chemical product and approval of the product label if: d) the chemical product is similar to a registered chemical product; and e) chemistry and manufacture data, efficacy data and target species safety data are the only data required to demonstrate the similarity of the chemical product to the registered chemical product; and f) for an application mentioned in paragraph (b) the active constituent complies with a monograph or compendial standard in the British Pharmacopoeia, British Pharmacopeia (Veterinary), European Pharmacopoeia or United States Pharmacopeia; and g) for an application mentioned in paragraph (c), a separate application for the approval of the active constituent in the chemical product has been lodged.	8 months	4 870	7 566

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
Item 6	a) Registration of a chemical product containing an approved active constituent and approval of the product label; or b) Registration of a chemical product and approval of the active constituent in the chemical product and approval of the product label; or c) Registration of a chemical product and approval of the product label if: d) the chemical product is closely similar to a registered chemical product; and e) chemistry and manufacture data are the only data required to demonstrate the similarity of the chemical product to the registered chemical product; and f) for an application mentioned in paragraph (b) the active constituent complies with a monograph or compendial standard in the British Pharmacopoeia, British Pharmacopeia (Veterinary), European Pharmacopoeia or United States Pharmacopeia; and g) for an application mentioned in paragraph (c) a separate application for the approval of the active constituent in the chemical product has been lodged	8 months	4 290	6 406
Item 7	Application for registration of a chemical product containing approved active constituent/s and approval of the product label if: the product is closely similar to a registered chemical product; and efficacy and safety data are not required to demonstrate the similarity of the product to the registered product; and chemistry and manufacture data are not required.	3 months	1 755	2 632
Item 8	Application for registration of a chemical product containing approved active constituent/s and approval of the product label if: the product is the same as a registered chemical product; and the product is to be registered with a different product name.	3 months	1 655	2 632

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
Item 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.8U of the Agvet Code.	2 months	1 595	2 632
Item 10	For all situations other than those described in items 1–9: a) Registration of a chemical product containing an approved active constituent and approval of the product label; or b) Registration of a chemical product and approval of the active constituent in the chemical product; or c) Registration of a chemical product and approval of the product label (but only if a separate application for the approval of the active constituent in the chemical product has been lodged).	Modular assessment period	Modular assessment fee	Modular assessment fee
Item 10A	Application for approval of a label for containers for a registered chemical product.	Modular assessment period	Modular assessment fee	Modular assessment fee
Application to vary a registration or label approval				
Item 11	Application to vary particulars or conditions of registration and/or label approval where a full assessment of the chemical product is required.	10 months	28 610	36 205
Item 12	Application to vary particulars or conditions of registration and/or label approval if: the variation is to allow a minor change; and no data of a technical nature is required.	3 months	1 170	2 018
Item 13	Application to vary particulars or conditions of registration or listed registration and/or label approval if: the variation is to allow a minor change; and no data of a technical nature is required; and the variation is a change required by the APVMA.	3 months	Nil fee	Nil fee
Item 13A	Application to vary a relevant particular of an approval or registration where the relevant particular is a prescribed variation.	1 months	175	175

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
Item 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 Items 11–13A.	Modular assessment period	Modular assessment fee	Modular assessment fee
Application for approval of an active constituent				
Item 15	Application for approval of an active constituent requiring a full assessment.	14 months	30 550	38 776
Item 16	Application for approval of an active constituent requiring less than a full assessment but requiring a toxicological assessment	9 months	18 805	27 031
Item 17	Application for approval of an active constituent other than as described in Items 15 or 16.	7 months	3 155	5 442
Item 18	Application to vary particulars or conditions of an approved active constituent.	7 months	2 465	4 252
Application for a permit				
Item 19	Application for a permit extension of 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, where no data of a technical nature is required	3 months	350	350
Item 20	Application for a permit, or extension of a permit, where a previous assessment remains valid and no data of a technical nature is required.	3 months	350	350
Item 21	Application for a permit, or extension of a permit, where the proposed use is a Minor Use.	Modular assessment period	350	350
Item 22	Application for a permit, or extension of 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
Item 23	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the application is not of a kind described in any of Items 19 to 21.	Modular assessment period	Modular assessment fee	Modular assessment fee

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
Other applications				
Item 24	Approval or registration under section 10 of the Code requiring assessment of a technical nature (other than of the kinds described in any of items 1 to 10, 15, 16 or 17)	Modular assessment period	Modular assessment fee	Modular assessment fee
Item 25	Application for a technical assessment made under regulation 8AS	Modular assessment period	Modular assessment fee	Modular assessment fee
Item 27	Timeshift application (see definition of time shift application. PAA is required).	Modular assessment period	Modular assessment fee	Modular assessment fee
Item 28	Applications made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination.	Modular assessment period	Modular assessment fee	Modular assessment fee
Item 29	Application made under regulation 19AEB to make an interchangeable constituent determination.	Modular assessment period	Modular assessment fee	Modular assessment fee
Modules				
Module 1	Preliminary assessment	n/a	710	902
Module 2.1	Chemistry—Level 1	13 months	9 220	11 074
Module 2.2	Chemistry—Level 2	9 months	3 075	3 075
Module 2.3	Chemistry—Level 3	6 months	1 580	1 954
Module 3.1	Toxicology—Level 1	13 months	27 920	27 920
Module 3.2	Toxicology—Level 2	9 months	15 795	15 795
Module 3.3	Toxicology—Level 3	5 months	4 050	4 050
Module 4.1	Toxicology—requiring poison schedule classification	13 months	2 435	2 435
Module 5.1	Residues—Level 1	13 months	18 170	25 650
Module 5.2	Residues—Level 2 (Registration only)	8 months	10 525	11 149
Module 5.3	Residues—Level 3 (Permit only)	8 months	8 200	16 400
Module 5.4	Residues—Level 4 (Registration only)	4 months	7 465	7 465

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
Module 5.5	Residues—Level 5 (Permit only)	4 months	2 000	4 000
Module 6.1	OH&S—Level 1	13 months	4 410	8 820
Module 6.2	OH&S—Level 2	7 months	3 185	3 185
Module 6.3	OH&S—Level 3	4 months	2 910	3 913
Module 7.1	Environment—Level 1	13 months	26 390	26 390
Module 7.2	Environment—Level 2	7 months	7 315	7 659
Module 7.3	Environment—Level 3	4 months	1 720	2 979
Module 8.1	Efficacy and Safety—Level 1	6 months	2 370	4 740
Module 8.2	Efficacy and Safety—Level 2	4 months	975	1 950
Module 8.3	Efficacy and Safety—Level 3	3 months	580	1 160
Module 9	Non-food trade	6 months	1 175	1 175
Module 10.1	Special Data—Level 1	13 months	Nil fee	Nil fee
Module 10.2	Special Data—Level 2	7 months	Nil fee	Nil fee
Module 10.3	Special Data—Level 3	7 months	Nil fee	Nil fee
Module 11.1	Finalise—Type 1	3 months	4 055	8 110
Module 11.2	Finalise—Type 2 (Registration only)	2 months	1 545	3 090
Module 11.3	Finalise—Type 3 (Permit only)	2 months	865	1 730
Module 12	Data Protection	n/a	460	460
Other fees				
HGP	Application/ renewal fee	n/a	305	429
Certificate of Export	Requires technical assessment	n/a	125	125
Certificate of Export	No technical assessment	n/a	230	230
GMP Audit	Assessment fee—Item 1 and Multi-Item 2–4	n/a	7 500	7 500
GMP Audit	Assessment fee—Single Item 2–4	n/a	5 000	5 000

Item/Module/ Other Cost Recoverable Service	Description of application	Current period	Current fee ($)	Fee proposed from 1 July 2020 ($)
GMP Audit	Assessment fee—Item 6	n/a	1 800	1 800
GMP Foreign Audit	Assessment fee	n/a	1 000	1 000
GMP Licence	Application fee	n/a	900	900
GMP Supplemental Audit	Review fee	n/a	1 800	1 800

Proposed revised cost recovery arrangements from 1 July 2020

The following table provides a complete summary of the APVMA's proposed cost recovery arrangements to take effect from 1 July 2020.

Note: The estimated fee revenue from Items and Modules are not mutually exclusive. In most cases, Module fee revenue has been accounted for in estimated Item fee revenue and so there is some overlap. It is not possible to estimate some Item fee revenue with any confidence if this revenue is Module demand dependent.

Table 18: Proposed Item cost recovery arrangements from 2020–21 (full year)

Item Recoverable Service	Est Volume	Proposed Fee ($)	Method of Cost Recovery	Estimated Fee Revenue 2020–21 ($)	Estimated Total Cost 2020-21 ($)
ITEM					
Item 1	2	116 501	Fee	233 002	477 218
			Levy	244 216	
Item 2	33	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 3	1	83 511	Fee	83 511	173 983
			Levy	90 472	
Item 4	1	44 644	Fee	44 644	110 859
			Levy	66 215	
Item 5	40	7 566	Fee	302 640	785 747
			Levy	483 107	
Item 6	52	6 406	Fee	333 112	853 332
			Levy	520 220	
Item 7	341	2 632	Fee	897 512	2 269 370
			Levy	1 371 858	
Item 8	164	2 632	Fee	431 648	1 091 427
			Levy	659 779	

Item Recoverable Service	Est Volume	Proposed Fee ($)	Method of Cost Recovery	Estimated Fee Revenue 2020–21 ($)	Estimated Total Cost 2020-21 ($)
Item 9	3	2 632	Fee	7 896	19 965
			Levy	12 069	
Item 10	236	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 10A	57	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 11	1	36 205	Fee	36 205	98 057
			Levy	61 852	
Item 12	394	2 018	Fee	795 092	2 622 087
			Levy	1 826 995	
Item 13	88	0	Registration renewal fee	585 644	585 644
Item 13A	516	175	Fee	90 300	3 434 002
			Levy	3 343 702	
Item 14	297	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 15	1	38 776	Fee	38 776	78 841
			Levy	40 065	
Item 16	3	27 031	Fee	81 093	186 641
			Levy	105 548	
Item 17	120	5 442	Fee	653 040	1 983 269
			Levy	1 330 229	
Item 18	104	4 252	Fee	442 208	1 200 145
			Levy	757 937	
Item 19	24	350	Fee	8 400	159 721
			Levy	151 321	

Item Recoverable Service	Est Volume	Proposed Fee ($)	Method of Cost Recovery	Estimated Fee Revenue 2020–21 ($)	Estimated Total Cost 2020-21 ($)
Item 20	192	350	Fee	67 200	1 277 768
			Levy	1 210 568	
Item 21	202	350	Fee	70 700	1 411 785
			Levy	1 341 085	
Item 22	64	0	Registration renewal fee	425 923	425 923
Item 23	64	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 24	0	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 25	19	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 27	12	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 28	0	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Item 29	0	The modular assessment fee	Fee and levy	Module demand dependent	Module demand dependent
Total Item					**$19 245 784**
Total Module					**$10 017 419**
Total Item and Module					**$29 263 203**

Table 19: Proposed other cost recovery arrangements from FY2020–21

Other Recoverable Service	Est Volume	Proposed Fee ($)	Method of Cost Recovery	Estimated Fee Revenue 2020–21 ($)	Estimated Total Cost 2020–21 ($)
OTHER					
Compliance and enforcement			Registration renewal fee and levy	2 575 588	2 575 588
Chemical Review and AERP			Registration renewal fee and levy	3 543 910	3 543 910
HGP notification number application and renewal	215	429	Fee	92 235	92 235
Certificate of Export (requires technical assessment)	40	230	Fee	9 200	71 712
			Levy	62 512	
Certificate of Export (no technical assessment)	40	125	Fee	5 000	39 028
			Levy	34 028	
GMP Audit Assessment fee—Item 1 and Multi-Item 2–4	65	7 500	Fee	487 500	367 401
			Levy	-120 099	
GMP Audit Assessment fee—Single Item 2–4	40	5 000	Fee	200 000	244 934
			Levy	44 934	
GMP Audit Assessment fee—Item 6	65	1 800	Fee	117 000	88 176
			Levy	-28 824	
GMP Foreign Assessment fee	360	1 000	Fee	360 000	205 901
			Levy	-154 099	
GMP Licence Application	10	900	Fee	9 000	160 811
			Levy	151 811	
GMP Supplement Audit Review	2	1 800	Fee	3 600	113 917
			Levy	110 317	
Total Other					**$7 503 613**
GRAND TOTAL					**$36 766 816**

4 RISK ASSESSMENT

The overall risk rating for the CRIS is medium because:

- the proposed change in annual cost recovery revenue for the regulatory activity is between five per cent and 10 per cent
- the revised cost recovery charges only impact some existing activities, all of which are already subject to cost recovery.

The total annual cost recovery revenue for the activity is approximately $35 million.

4.1 Risk mitigation

While reviews of cost recovery arrangements are usually required to be undertaken every five years, the Department of Finance also requires ongoing reviews of fees and charges to be undertaken.

Data generated from this review process will be used to make timely adjustments to fees and charges.

Any broader changes to the APVMA's functional responsibilities will trigger the need for a wider review. Where a material amendment is made to these cost recovery arrangements, a new CRIS will be prepared in accordance with the Cost Recovery Guidelines.

5 STAKEHOLDER ENGAGEMENT

The Australian Pesticides and Veterinary Medicines Authority (APVMA) commenced the current CRIS review in 2017 with the commissioning of PricewaterhouseCoopers (PwC) to review the cost recovery arrangements. Since this review, a range of discussion papers and consultation sessions have occurred with key stakeholders. A summary of this consultation is outlined below.

- PwC Review of Cost Recovery Arrangement—October 2017
- APVMA financial sustainability plan and the APVMA financial stability paper released June—August 2018
- various discussions at ARAC, roundtables and board meetings throughout 2018–19
- CRIS 2019 discussion paper circulated 28 August 2019
- discussion forum of 3 September 2019
- cost model report circulated 4 September 2019
- revised discussion paper circulated 25 September 2019
- draft CRIS circulated 4 November 2019 (options one, two and three)
- summary of feedback on draft CRIS circulated 17 December 2019
- discussion forum of 19 December 2019.

The following parties provided written submissions in relation to the draft CRIS:

- Accord
- Animal Medicines Australia (AMA)
- CropLife
- National Farmers' Federation (NFF)
- Veterinary Manufacturers and Distributors Association (VMDA).
- Agprotect Australasia Pty Ltd
- Pesticide Action Group of Western Australia (PAGWA)
- Grain Producers Australia (GPA)
- 4 Farmers Australia Pty Ltd (contents of submission provided in confidence)
- Yates Australia
- John Harvey.

5.1 Support for the agvet chemical regulatory framework

Overall, stakeholders supported the need for a robust, effective and efficient agvet chemical regulatory scheme and the need for cost recovery arrangements to underpin this scheme.

5.2 Consultation and implementation timeframes

Stakeholders expressed concerns regarding the proposed implementation date of 1 March 2020. Some raised concerns about the ability of the sector to absorb price increases, particularly this financial year.

Consequently, the revised CRIS implementation date will be deferred until 1 July 2020.

Although some indicated the consultation process had been inadequate others acknowledged the strength of the consultation process, and in particular, the willingness of the APVMA to include a third option for consideration at the request of industry stakeholders.

5.3 Consideration of previous reviews

Stakeholders acknowledged the previous work and reviews undertaken in relation to the APVMA's cost recovery arrangements.

Some stakeholders would have liked a broader discussion regarding the overall architecture underpinning the APVMA's cost recovery arrangements while others acknowledged that there will be an opportunity for this to occur through the First Principles Review into agvet chemical regulation that is currently underway.

Stakeholders expressed a range of views regarding the appropriate mix of revenue from fees, levies and other charges.

5.4 Efficiency of the APVMA

Stakeholders agreed on the importance of a robust and efficient regulator. Some stakeholders sought further information in relation to the efficiency of the APVMA's operations and its overall financial position.

5.5 Public good

A range of stakeholders raised concerns about the use of cost recovery funds to address objectives of a broader social or public good.

5.6 Other issues

One respondent raised legal concerns with the APVMA's cost recovery arrangements, the extent of the duty to consult with the intergovernmental agreement partners, and the APVMA's obligation as a Corporate Commonwealth Entity.

Some respondents raised concerns about the APVMA collecting revenue from the entities that it regulates.

6 RESPONSE OF THE APVMA TO STAKEHOLDER FEEDBACK

The current cost recovery arrangement for the APVMA came into effect on 1 July 2013. Since the introduction of the new CRIS, there has been no increase to fees, levies or other charges since 1 January 2015.

Industry has been made aware for some time that the APVMA was not fully recovering its costs, which would necessitate revised cost recovery arrangements to ensure the APVMA was complying with the Government Policy Order to fully cost recover its activities.

An independent review of the current cost recovery arrangements found that the prices set in the current CRIS were no longer consistent or reflective of the true costs of undertaking activities.

In mid-2018, the APVMA released a Financial Stability Plan. This plan identified that an increase in fees and charges would be required. The paper identified that the magnitude of this increase would be in the order of 10 to 15 per cent and the increases would need to occur from FY2019–20 onward.

A draft discussion paper outlining possible pricing models for the CRIS was released in August 2019 and stakeholder sessions were held following its release. The key feedback from stakeholders at these sessions related to:

- the timeframes for implementation
- the need to minimise any impact in the first year of implementation
- the need to look at an additional option which would recover a greater proportion of funds from applications fees rather than the registration renewal fee.

In response to this feedback the APVMA drafted a revised discussion paper to address these concerns and released a draft CRIS on 4 November 2019. In response to stakeholder feedback on the revised CRIS:

- the APVMA reduced the overall financial impact in the first year (FY 2019–20) from $2.6 million to $1.5 million for Option one; and
- introduced a third option, which provided for a greater proportion of the additional revenue to come from application fees.

The APVMA acknowledges the need for stakeholders to fully understand the costs of the agency’s operations and has released the full cost model underpinning the draft CRIS 2020.

The APVMA is confident it is meeting all its legal requirements in relation to cost recovery, consultation and the *Public Governance, Performance and Accountability Act 2013*.

The APVMA acknowledges the need for efficient regulation. In the range of consultations held with stakeholders throughout 2018 and 2019, industry has consistently reiterated the primary objective of the APVMA should be the quality, timeliness and predictability of its decision-making.

The APVMA has sought to achieve efficiencies in its operations over recent years, and has invested these efficiencies back into improving operations, rather than replenishing its cash reserves or rebuilding its balance sheet. This reinvestment has yielded significant productivity improvements for registrants:

- timeframe performance has improved from a low of 58 per cent in June 2017 to a consistent 85 per cent of applications approved within timeframe over the past 18 months
- the total average time taken to process an application has decreased from 7.6 months in 2015–16 to 5.6 months in 2018–19
- the total number of overdue major product registration applications has declined from 223 in July 2017 to near 50, and the proportion of work in progress within timeframe for all product applications has improved from 67 per cent to 92 per cent in the same period.

The APVMA continues to invest in efficiency improvements particularly through its investment in improved business processes and IT solutions.

The APVMA acknowledges the climatic conditions throughout Australia and the recent prolonged drought faced by many farmers. While any increase in fees is understandably of concern to stakeholders, the APVMA disagrees with the assertion the proposed fee increases are significant.

The APVMA notes the Department of Finance has approved the APVMA's proposed cost recovery model as compliant with the Cost Recovery Guidelines, and that it is supported by rigorous expense, effort and cost data.

Moreover, relocation and digital transformation costs have been, and will continue to be, met through appropriation funding over the life of the proposed CRIS and there has not been a cross subsidisation of these expenses by registrants.

The APVMA acknowledges that stakeholders are seeking broader engagement on the cost recovery model. Following finalisation of the 2020 CRIS, the APVMA is committed to establishing a working group with key stakeholders to consider future funding models. This will be an important mechanism for engagement, and will assist the APVMA in providing advice to the Independent Review Panel about future funding models. The APVMA welcomes a discussion with industry about the use of cost recovered funds for broader public and social benefit as part of these discussions.

7 FINANCIAL ESTIMATES

7.1 Forecast operating results of cost recovery arrangements

The financial estimates in Table 20 show the expenses of the full cost recovery approach, and other activities funded through own source income.

Note: Table 20 does not carry forward the cumulative deficits since prices were last adjusted in FY2014–15.

Table 20: Forecast operating results FY2020–21 to FY2021-22

	2020–21 $'000	2021–22 $'000
Total income	37 854	38 836
Total expenses	37 828	38 836
Surplus/(Deficit)	26	0

7.2 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 maintain a financial reserve (which forms part of its equity). Without this financial reserve, the APVMA would risk periods of time where its liabilities could exceed its assets and result in negative equity.

The financial reserve proposed is based on three months of operating expenses (working capital) and is currently set at $9.0 million.

8 PERFORMANCE

8.1 Financial performance

The Charging Framework applies to all non-corporate Commonwealth entities and selected corporate Commonwealth entities. It includes performance requirements based on Section 38 of the *Public Governance, Performance and Accountability Act 2013* (the PGPA Act), which is 'Measuring and assessing performance of Commonwealth entities'. These requirements include:

- the accountable authority of a Commonwealth entity must measure and assess the performance of the entity in achieving its purposes
- the measurement and assessment must comply with any requirements prescribed by the rules.

The data reveals that annual revenue received from charges (fees and levies) to industry for regulatory services provided has not recovered the costs of providing those services. The impact has been an erosion of the financial reserves of the entity to a point where the working capital buffer is now less than the threshold $9.0 million and it is likely to be further eroded in the absence of additional revenue (from fees and levies) being available to fully recover recurring necessary operating costs of regulatory service delivery.

Table 21 shows actual operating results from 2014–15 to 2018–19. Over this period the APVMA received around $15 million of additional funding from Government. Excluding that funding, there was an average annual operating loss of around $2.2 million for normal operating activities over the period.

Table 21: Actual operating results FY2014–15 to FY2018–19

	2014–15 $'000	2015–16 $'000	2016–17 $'000	2017–18 $'000	2018–19 $'000
Expenses	33 204	33 855	36 015	39 908	47 337
Revenue	29 741	30 546	35 055	39 195	57 368
Surplus/(Deficit)	**(3 463)**	**(3 309)**	**(960)**	**(713)**	**10 031**
Less: Unspent NPP funds					(12 515)
Surplus/(Deficit)	**(3 463)**	**(3 309)**	**(960)**	**(713)**	**(2 484)**
Other Comprehensive Income	5 155	131	(201)	(167)	(48)
Surplus/(Deficit)	**1 692**	**(3 178)**	**(1 161)**	**(880)**	**(2 532)**

8.2 Non-financial performance

The APVMA is continuously reviewing and improving the way the organisation operates, and how regulatory services can better meet the needs of the agvet industry and the Australian community.

The APVMA has consistently improved its assessment timeframe performance since late 2017. In 2018–19 we improved our regulatory processes with 85 per cent of applications processed within statutory timeframes, and we finalised around 3000 applications. We processed 7126 adverse experience reports and took regulatory action on one product family to ensure that its use remains safe and efficacious. The APVMA also completed its chemical review into chlorpyrifos and cancelled the use of chlorpyrifos in domestic and home garden settings, and in some public spaces.

As part of the CRIS process, the APVMA has also reviewed the cost of its operations. We have put in place measures to improve the efficiency of our operations while also improving our overall assessment performance. These measures include:

- reducing the size of our corporate services team from around 40 staff to 25 staff under the new APVMA Business Operating Model
- increasing the use of international assessments within the APVMA. Reliance on international assessments has been invaluable in reducing processing times, in some cases resulting in a significant time saving where, for example, an earlier than expected scheduling date has been met, resulting in an early finalisation of the application process
- introducing automation to improve the efficiency of business processes through the APVMA Enabling Technology program.

The APVMA's self-assessment against key performance indicators (KPIs) are detailed in its Annual Report 2018–19 and published online.

9 KEY FORWARD DATES AND EVENTS

- 1 July 2020—Revised CRIS implemented
- October 2020—Next scheduled update of actual results—Annual Report
- February 2021—Independent review of the agvet chemical regulatory framework to deliver final report to Minister.

10 CRIS APPROVAL AND CHANGE REGISTER

The CRIS approval and change register is captured in Table 22, and details the dates, basis and approver for changes to the CRIS.

Table 22: CRIS approval and change register

Date of CRIS change	CRIS change	Approved	Basis for change
13/12/2019	Policy approval	Prime Minister	Approval to amend how the APVMA recovers its regulatory costs
10/03/2020	Certification of the CRIS	Acting CEO APVMA	Updated registration renewal fees and some other fees and charges from 1 July 2020
8/04/2020	Agreement to the CRIS	Minister for Agriculture, Drought and Emergency Management	Approval to change registration renewal fees and some other fees and charges from 1 July 2020

Page left blank

Appendix

GLOSSARY OF TERMS AND ABBREVIATIONS

ABC	The APVMA's 2019 Activity Based Costing model used to establish the cost of current activities
AERP	Adverse Experience Reporting Program
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
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 Items: • 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.
CRG	Cost Recovery Guidelines
CRIS	Cost Recovery Implementation Statement. A statement documenting compliance with the cost recovery policy.
Department of Agriculture	Australian Government Department of Agriculture
GMP	Good Manufacturing Practice
Guidelines	Australian Government Cost Recovery Guidelines (July 2014)
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.
Information activities	Activities involved in collecting, compiling and disseminating information or any other activity of a non-regulatory nature.
MLS	Manufacturer's 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.
PGPA Act	Public Governance, Performance and Accountability Act 2013
PGPA Act entities	Entities and companies that are financially part of the legal entity of the Commonwealth and are subject to the PGPA Act.
Regulatory activities	Activities involved in administering regulations
SAS	Scientific Assessment Services
Vet	Veterinary