Australian Government

Australian Pesticides and Veterinary Medicines Authority

Cost Recovery Implementation Statement (CRIS)

Evaluation and registration of agvet chemicals and their regulation up to and including point of sale for the financial years

1 February 2023 to 30 June 2025

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.

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This publication is available from the APVMA website.

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Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) outlines how the Australian Pesticides and Veterinary Medicines Authority (APVMA) implements 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.

This CRIS provides financial forecasts for the reporting period FY 2022–23 to FY 2024–25. This CRIS sets out the government's commitment to ensure cost recovery revenue is allocated to deliver demand-driven regulatory activities efficiently and effectively.

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 some veterinary product sales tends to be stable, whereas the wholesale value of agricultural product sales tends to be closely linked to seasonal and economic conditions. Periods of lower-than- or, higher-than average agvet chemical sales directly causes a change in levy revenue yield in the following year as it is based on the immediate past year product sales revenue.

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 functions of the APVMA, which are set out in section 7 of the Administration Act, are to:

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

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

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

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

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

l) 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.

On 7 March 2022, measures from the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021* commenced. These include measures to:

- provide for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses of chemical products – particularly those uses (minor uses) with insufficient commercial return for chemical companies to normally add to the product label (part 3)
- reduce the regulatory burden by enabling the APVMA to grant part of a variation application under section 27 of the Schedule to the Code Act (part 7)
- enable a person to apply to vary an approval or registration that is suspended, to the extent that the variation relates to the grounds for suspension (part 8)
- establish civil pecuniary penalties for contraventions of provisions in the Agvet Code and the Administration Act relating to providing false or misleading information to the APVMA (part 9)
- provide the APVMA with more comprehensive grounds for suspending or cancelling approvals or registrations where information is provided in a variation application that is false or misleading (part 10)

- optimise risk communication about chemical products by improving the transparency of voluntary recalls (part 11)
- harmonise the need to inform the APVMA of new information (where it relates to the safety criteria) so that the same obligations apply to all holders and applicants (part 12).

A list of all measures in the Improvements Act, and the expected implementation dates is available on the APVMA website. The costs associated with the new bill have been accommodated within the current APVMA budget.

The establishment of a new APVMA Board was proclaimed by the Governor-General on 3 March 2022. From 4 March 2022, the Accountable Authority of the APVMA is the Board under the *Public Governance, Performance and Accountability (PGPA) Act 2013*. Schedule 2 of the Improvements Act describes the APVMA Board and how it will be established and operate. The Board is the body established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* to govern the APVMA and conduct financial, risk and audit oversight amongst other functions and duties.

Regulatory functions and services

The APVMA's regulatory functions are summarised in the following paragraphs. More details of the regulatory services are available in the Cost Recovery Model section of this document.

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 must 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, Fisheries and Forestry. 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 and governance 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.

Policy and statutory authority to cost recover

Government policy approval to recover the costs of the regulatory activity

The Australian Government's overarching cost recovery policy is that, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of those activities. The cost recovery policy promotes consistent, transparent, and accountable charging for government activities and supports the proper use of public resources.

The APVMA is a corporate Commonwealth Entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and the Finance Minister has made a 'government policy order' that the agency must apply the Australian Government's cost recovery policy and charging framework.

The government's Cost Recovery Guidelines (the CRGs) set out the overarching framework under which the APVMA designs, implements and reviews cost recovered activities provided on behalf of the Australian Government.

The Department of Finance has published the following Resource Management Guides (RMGs) which contain the mandatory principles or requirements of the CRGs:

RMG 304: Australian Government Cost Recovery Guidelines – July 2014 – Third edition

RMG 302: Australian Government Charging Framework – July 2015

The agency generally sets fees and charges to recover the full cost of a service provided directly to a specific individual or organisation except for fee-for-service regulatory activities where the Australian Government has made an explicit policy decision to allow the agency to charge for part of the cost of each activity.

The APVMA has been granted policy approval to partially cost recover its fee-for-service regulatory activities at an average of 40%, with the balance of regulatory costs recovered from statutory levies. The registration and approval of agvet chemical products are the APVMA's main fee-for-service regulatory activities where this policy is applied.

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.

The Administration Act, the Agvet Code, the Agvet Code Regulations, and the Agvet Codes and Agvet Regulations of each state and participating territory confer functions and powers on the APVMA. The APVMA's fee structure is authorised by several 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 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) – that 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 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.

Good Manufacturing Practice (GMP) – manufacture licensing

GMP Audit Assessment fees as pursuant to 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.

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.

Cost recovery model

Cost recovery fee or levy

The characteristics of the agency's activity determine the type of cost recovery charge used. There are 2 types of cost recovery charges:

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 (e.g., an industry sector) rather than to a specific individual or organisation. A cost recovery levy is a tax and 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.

Outputs of APVMA's regulatory charging activities

The APVMA considers registration and approvals in the following categories:

- Agvet chemical active constituents
- Agricultural and veterinary chemical products
- Permits

In addition to the registration and approval of veterinary chemical products, the APVMA administers the Manufacturer's Licensing Scheme, which issues licences to manufacturers of veterinary chemical products and audits their compliance with the Code of Good Manufacturing Practice (GMP).

These activities are, in part, funded directly through fees paid by applicants, and services are considered to confer an exclusive capturable commercial benefit on an applicant.

The APVMA also issues import and export permits for agricultural and veterinary chemicals.

Other functions that result in 'outputs' and are conducted by the APVMA may be considered essential deliverables for robust regulation but are not considered to confer such a benefit on an individual applicant.

- Chemical review
- Assessment, Investigations and Monitoring (post-market)

A summary of the APVMA's regulatory charging activities classified as Pre and Post Market regulatory functions are shown Table 1.

Table 1: The APVMA's regulatory functions and services

Functions	Activities	Outputs (services)
Pre-market regulation	Registration and approvals	Registration and approvals – evaluation of applications (including permits)
		Certificates of Export
		Consents to Import
		Pre-application assistance
Post-market regulation	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 and governance	Information activities	Corporate publications
		Informing policy
		Presentations and seminars
		Website

Details of the 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 (duration) periods 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,	Approximately 40% of costs recovered by fees with the remaining funded by levies.
	Variations to registered products	11, 12	
		13	No charge for this application Item. The cost of processing these applications is funded by registration renewal fees.

Type of application	Item	Cost recovery mechanism
	13A	Fixed fee ($175) for these application Items with the remaining costs funded by levies.
	14	Approximately 40% of costs recovered by fees with the remaining funded by levies.
Active applications	15, 16, 17, 18	
Permit applications	19, 20, 21	Fixed fee ($350) for these application Items with the remaining costs funded by levies.
	22	No charge for this application Item. The cost of processing these applications is funded by levies.
	23	Approximately 40% of costs recovered by fees with the remaining funded by levies.
Other applications	24	
Technical Assessment	25	
Timeshift applications	27	
Ingredient determination	28	
Interchangeable constituent determination	29	

Items 1 to 14 (product applications)

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

Items 15 to 18 (active constituent applications)

Items 15 to 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 to 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 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, 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
- 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 to 23, or 27 to 29. Item 24 currently applies for applications made under section 10 (approval and registration applications), this CRIS proposes to expand item 24 to cover applications made under section 27 (variation applications).

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 costs of Consent to Import services are funded by registration renewal fees.

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 with the residual cost recovered from the levies.

Monitoring ongoing compliance with regulations

Evaluation of applications for Good Manufacturing Practice

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

Hormonal Growth Promotant Scheme

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

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

Adverse Experience Reporting Program

The full cost of the Adverse Experience Reporting Program (AERP) is recovered from registration renewal fees and the levies.

Chemical Review Program

The full cost of the Chemical Review Program is recovered from registration renewal fees and levies.

Investigation and enforcement

The full cost of investigation and enforcement is recovered from appropriation, registration renewal fee and levies.

Information activities

The full cost of the information activities is recovered from registration renewal fees and levies.

Agency enabling activities used to deliver outputs

Agency enabling activities are business processes that relate to the whole of the APVMA. These activities include:

- business improvement
- corporate planning and performance
- finance and procurement
- Freedom of Information (FOI) requests and privacy
- general counsel (legal)
- human resources
- information technology and communication (ITC)
- parliamentary, media and communications
- records and knowledge management
- reform and engagement.

Agency enabling activities support the APVMA in its delivery of services to individuals, organisations and the agvet industry, and its performance of other regulatory activities. By their nature, the costs of these activities are not directly attributable to services provided nor regulatory activities in relation to specific individuals or organisations.

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 registration 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.
- Agency enabling activities connected to the services and regulatory functions were identified in consultation with relevant corporate management and staff.
- Staff salary and on costs are mostly a fixed cost and allocated to activities based on the apportionment of staff estimated effort (time) spent on activities.
- Actual supplier costs.
- Agency enabling activities and other overhead costs were charged to outputs based on suitable and appropriate drivers, where it can be reliably attributed to the activity.
- Unit prices for this CRIS were based on average volume actuals over a 5-year period including FY2021–22.

Cost components

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

- **Direct costs:** 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 (e.g. 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 recovered from a combination of application fees and levies, with most of the costs recovered through levies. The Australian Government, states and territories agreed that the costs of assessing applications should be collected in 2 parts: 40% of the assessment costs being charged as an upfront application fee and the balance of revenue required to fund the activity recovered by levies.

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 FY2022-23 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	15,103,178
Suppliers	Outsourced activities—scientific assessment services undertaken by external agencies	Direct Cost	1,470,730
Overheads		Indirect Cost	10,040,889
Total			**26,614,797**

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

The FY2022–23 estimated costs for pre-application assistance activities are shown below in Table 4.

Table 4: Cost components of pre-application assistance

Expense	Inclusions	Attribution	Annual cost ($)
Service: Pre-application assistance			
Employee expenses	Technical and administrative assessment costs	Direct Cost	954,683
Suppliers	Outsourced activities	Direct Cost	93,077
Overheads		Indirect Cost	634,716
Total			**1,682,476**

Certificates of Export

The FY2022–23 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	107,530
Suppliers	Outsourced activities	Direct Cost	–
Overheads		Indirect Cost	69,242
Total			**176,772**

Consents to Import

No fee is charged for this service. The costs of Consent to Import activities is funded by annual product registration renewal fee.

Monitoring ongoing compliance with regulations

Evaluation of applications for Good Manufacturing Practice

The FY2022–23 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	1,098,551
Suppliers	Outsourced activities	Direct Cost	42,000
Overheads		Indirect Cost	704,472
Total			**1,845,023**

Hormonal Growth Promotant Scheme

The FY2022–23 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	70,155
Suppliers	Outsourced activities	Direct Cost	–
Overheads		Indirect Cost	–
Total			**70,155**

Adverse Experience Reporting Program and Chemical Review Program

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

The FY2022–23 estimated costs for the Adverse Experience Reporting Program (AERP) are shown in Table 8 and Chemical Review in Table 9.

Table 8: Cost components of the AERP

Expense	Inclusions	Attribution	Annual cost ($)
Service: AERP			
Employee expenses	Review work	Direct Cost	232,714
Suppliers	Outsourced activities	Direct Cost	–
Overheads		Indirect Cost	195,348
Total			**428,062**

Table 9: Cost components of the Chemical Review Program

Expense	Inclusions	Attribution	Annual cost ($)
Service: Chemical Review			
Employee expenses	Review work	Direct Cost	823,683
Suppliers	Outsourced activities	Direct Cost	4,517
Overheads		Indirect Cost	695,220
Total			**1,523,420**

Investigation and enforcement

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

The FY2022–23 estimated costs for investigation and enforcement are shown in Table 10.

Table 10: 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	1,118,429
Suppliers	Outsourced activities	Direct Cost	195,467
Overheads		Indirect cost	1,102,930
Total			**2,416,826**

Information and regulatory 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 overhead where they can be reliably attributed to a fee funded output to the various programs of the APVMA.

Regulation governance is provided to a group of individuals, or organisations across the agvet industry sector rather than to a specific individual or organisation. The costs are recovered via levies to fund these activities provided to the sector.

Design of regulatory charges

APVMA cost recovery arrangements and fees-for-services are reviewed annually and formally updated, if required, through the CRIS process to ensure that the APVMA meets the principles and requirements of the Australian Government's Cost Recovery Guidelines and Charging Framework.

Fees for the registration and approval of chemical products, active constituents and associated product labels are set to partially recover the cost of these service activities at an average of 40%, with the balance of costs recovered from levies. The actual results, compared to the target of 40%, are influenced by volume and application types received from year to year.

The partial cost recovery of registrations and approvals costs the application of the policy approval that was granted to the APVMA on 13 November 2019. The policy aims to achieve a robust and sustainable funding model.

The registration and approval fees that took effect from 1 July 2020 were calculated in the previous CRIS, CRIS 2020-22, by applying this policy approval and took effect from 1 July 2020. No changes to the fees for registrations and approvals in CRIS 2022-25, except for the fee reductions resulting from the implementation of new and merged modules on 1 February 2023.

The fees for other services are set to recover the cost of those activities as required by the Australian Government's Cost Recovery Guidelines and Charging Framework. There are no changes in CRIS 2022-25 to the fees that took effect on 1 July 2020.

New modules and merging some modules

Consideration has been given to the module descriptors, the timeframes, and the relevant fees. The APVMA will introduce new modules to capture assessment types where a reduced timeframe and fee is considered appropriate.

An additional area of change is to consolidate the modules relating to toxicology and to work health and safety into 'health' modules. The terminology for Module 4 and 4.1 is also being changed from 'toxicology requiring poison schedule classification' to 'poison scheduling'. These changes reflect the current assessment processes within the APVMA.

Amendment to the Item 24 entry

The regulations setting out the assessment period and other details for item 24 type applications are currently restricted to applications made under section 10 of the Agvet Code (applications for registration, or approval of an active constituent or label) requiring assessment of a technical nature (other than those of the kinds described in any of table items 1 to 10, 15, 16 or 17). Hence it operates as a 'catch all' application type for applications made under section 10 of the Agvet Code that might, for some reason or other, not be caught by any of the other more specific application descriptions.

Item 24 type applications do not currently include an application made under section 27 of the Agvet Code (applications to vary the relevant particulars or conditions of an approved active constituent, label or registered chemical product). Similar to section 10 type applications, there is potential for a section 27 application to not meet any of the existing specific application descriptions. The addition of section 27 applications to the 'catch all' application type at item 24 will ensure any unintended gaps in the current application types is closed.

It will also allow full use of the new modules where these might not fit into the existing item structure. This is particularly important for chemistry applications to vary an approval active constituent as the current item 18 is not modular and would not allow for use of the chemistry modules as appropriate.

Levy rates

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 $5,000
- 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 levy and sale values declarations, 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 up to $5 000)	0.63%
Levy tier 1 (annual product sales up to $1 000 000)	0.63%

Based on sales	Current
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%

** The APVMA reserves the right to not collect levies on annual product sales up to $5,000 as it is not cost effective to do so.

Registration and approvals

The current CRIS aims to recover 40% of the costs of assessing applications 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 costs of Consent to Import services are funded by annual product registration renewal fees.

Certificates of Export

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

Table 13: Certificate of Export fees and charges from 1 February 2023

Type	Item	Number	Fee ($)	Fee revenue ($)
Service: Certificate of Export fees and charges				
Australian manufacturers	(no technical assessment)	243	125	55 890
Australian manufacturers	(requires technical assessment)		230	
Total				**55 890**

Good Manufacturing Practice

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

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

Table 14: GMP fees and charges from 1 February 2023

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 to 4	67	7 500	502 500
Australian manufacturers	GMP Audit Assessment Fee – Single Item 2 to 4	41	5 000	205 000
Australian manufacturers	GMP Audit Assessment Fee – Item 6 (Single-step manufacture)	66	1 800	118 800
Australian importers/registrants (per registrant/site)	GMP Foreign Audit Assessment Fee	361	1 000	361 000
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				**1 199 900**

* Some overseas sites have multiple GMP compliance assessments for several reasons (e.g., for different registrants using the same site or for different/additional product types).

Hormonal Growth Promotant scheme

Part of the cost of this activity is recovered by a direct fee which will remain at $429 from 1 February 2023.

Table 15: Hormonal Growth Promotant fees and charges from 1 February 2023

Type	Item	Forecast volume	Fee ($)	Fee revenue ($)
Service: Hormonal Growth Promotant fees and charges				
Australian manufacturers	HGP Notification number application and renewal	152	429	65 208
Total				**65 208**

Product registration renewal fee

The registration renewal fee is payable by 30 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 Item 13 applications as well as Consents to Import, and the costs associated with maintaining the product register.

Table 16: Registration renewal fee

	Payable annually	Payable for 5 years in advance
FY2020–21	*$550*	*$3 350*
FY2021–22	*$600*	*$3 650*
FY2022–23	$600	$3 650
FY2023–24	$600	$3 650

Estimated registration renewal fee revenue for one-year renewals is shown in Table 17 below.

Table 17: Estimated annual registration renewal fee revenue 2020–21 to 2022–23

	2020–21 Actual	2021–22 Volume Est	2022–23 Volume Est
Estimated number of registered products	12 330	12 853	12 853
Fee per registered product ($)	550	600	600
Total ($)	**6 781 500**	**7 711 800**	**7 711 800**

Implementation

The revised fees and charges regime will commence on 1 February 2023. New module application fee changes are presented in Table 19 and will apply to any new applications submitted from 1 February 2023.

Fees from 1 February 2023

The following tables provide a complete listing of the APVMA's revised fees from 1 February 2023.

Full module descriptors, including new modules, can be found on the APVMA website.

Table 18: Registration and application fees from 1 February 2023

Item	Description of application	Assessment period	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
Applications for approval of active constituent contained in a chemical product, registration of the chemical product and approval of the product label				
Item 1	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product	18 months	116 501	116 501
Item 2	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring less than full assessment of the active constituent and chemical product	Modular assessment period	Modular assessment fee	Modular assessment fee
Applications for registration of a chemical product containing an approved active constituent and approval of the product label				
Item 3	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is no registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required	18 months	83 511	83 511
Item 4	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is a registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required; and (c) there are no relevant maximum residue limits; and (d) poison schedule classification is required	18 months	44 644	44 644

Item	Description of application	Assessment period	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
Item 5	Application for: (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 Pharmacopoeia (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	7 566	7 566
Item 6	Application for: (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 closely similar to a registered chemical product; and (e) chemistry and manufacture data are the only data required to demonstrate the	8 months	6 406	6 406

Item	Description of application	Assessment period	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
	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 Pharmacopoeia (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			
Item 7	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are not required	3 months	2 632	2 632
Item 8	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is the same as a registered chemical product; and (b) the chemical product is to be registered with a different name	3 months	2 632	2 632
Item 9	Application for registration of a listed chemical product and approval of a product label where the product and label comply with an established standard that has been approved in accordance with section 8U of the Code	2 months	2 632	2 632
Item 10	Application for: (a) registration of a chemical product containing an approved active constituent and approval of the product label; or	Modular assessment period	Modular assessment fee	Modular assessment fee

Item	Description of application	Assessment period	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
	(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); for all situations other than those described in items 1 to 9			
Item 10A	Application for approval of a label for containers for a registered chemical product.	Modular assessment period	Modular assessment fee	Modular assessment fee
Applications for approval or registration for prescribed active constituents, chemical products or labels				
Item 10B	Application under subsection 14C(1), 14D(1) or 14E(1) of the Code	A period specified in, or worked out in accordance with, a legislative instrument made by the APVMA	An amount specified in, or worked out in accordance with, a legislative instrument made by the APVMA	An amount specified in, or worked out in accordance with, a legislative instrument made by the APVMA
Applications to vary a registration or approval				
Item 11	Application to vary relevant particulars or conditions of registration or label approval where a full assessment of the chemical product is required	10 months	36 205	36 205
Item 12	Application to vary relevant particulars or conditions of registration 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	2 018	2 018
Item 13	Application to vary relevant particulars or conditions of registration or label approval if: (a) the variation is to allow a minor change; and	3 months	Nil fee	Nil fee

Item	Description of application	Assessment period	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
	(b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA			
Item 13A	Application to vary a relevant particular of an approval or registration where the variation of the relevant particular is a prescribed variation under section 26B of the Code	1 months	175	175
Item 14	Application to vary relevant particulars or conditions of registration or label approval if the application is not of a kind described in any of items 11 to 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	38 776	38 776
Item 16	Application for approval of an active constituent requiring less than full assessment but requiring a toxicological assessment	9 months	27 031	27 031
Item 17	Application for approval of an active constituent requiring less than full assessment but not requiring a toxicological assessment (unless item 5, 6 or 10 applies)	7 months	5 442	5 442
Applications for variation to an approved active constituent				
Item 18	Application to vary relevant particulars or conditions of an approved active constituent	7 months	4 252	4 252
Application for a permit				
Item 19	Application for a permit, or 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	Description of application	Assessment period	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
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 22	Modular assessment period	Modular assessment fee	Modular assessment fee
Other applications				
Item 24	Application made under section 10 or 27 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 1 to 18)	Modular assessment period	Modular assessment fee	Modular assessment fee
Item 25	Application made under regulation 8AS for a technical assessment	Modular assessment period	Modular assessment fee, plus GST	Modular assessment fee, plus GST
Item 27	Timeshift application (see regulation 3BA)	Modular assessment period	Modular assessment fee	Modular assessment fee
Item 28	Application 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
Applications relating to holder or nominated agent				
Section 8L	Application to change the holder of an approval or registration		50	50
Section 8M	Application to nominate a nominated agent		50	50
Section 8P	Application to change a nominated agent		50	50
Lodgement of notifiable variations (NV's)			50	50

Table 19: Module fees from 1 February 2023

Module	Module, level, or type	Period for completion	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
1 Preliminary assessment		n/a	902	902
2 Chemistry				
2.1	Chemistry—level 1	13 months	11 074	11 074
2.2	Chemistry—level 2	9 months	3 075	3 075
2.3	Chemistry—level 3	6 months	1 954	1 954
2.4	Chemistry—level 4 (new module)	3 months		970
2.5	Chemistry—level 5 (new module)	2 months		480
3 Health				
3.1	Health—level 1 (new module)	13 months		36 740
3.1 (Superseded) *6.1 (Superseded)*	*Toxicology—level 1* *Work health and safety—level 1*	*13 months*	*27 920* *8 820*	
3.2	Health—level 2 (new module)	11 months		27 920
3.1 (Superseded)	*Toxicology—level 1*	*13 months*	*27 920*	
3.3	Health—level 3 (new module)	9 months		18 980
3.2 (Superseded) *6.2 (Superseded)*	*Toxicology—level 2* *Work health and safety—level 2*	*9 months* *7 months*	*15 795* *3 185*	
3.4	Health—level 4 (new module)	5 months		7 963
3.3 (Superseded) *6.3 (Superseded)*	*Toxicology—level 3* *Work health and safety—level 3*	*5 months* *4 months*	*4 050* *3 913*	
3.5	Health—level 5 (new module)	4 months		4 000
3.6	Health—level 6 (new module)	2 months		2 000
4. Poison scheduling				
4.1	Poison scheduling	13 months	2 435	2 435
5 Residues				
5.1	Residues—level 1	13 months	25 650	25 650
5.2	Residues—level 2	8 months	11 149	11 149

Module	Module, level, or type	Period for completion	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
5.3	Residues—level 3 (new module)	6 months		9 000
5.3 (Superseded)	*Residues—level 3*	*8 months*	*16 400*	
5.4	Residues—level 4	4 months	7 465	7 465
5.5	Residues—level 5 (new module)	3 months		2 000
5.5 (Superseded)	*Residues—level 5*	*4 months*	*4 000*	
7 Environment				
7.1	Environment—level 1	13 months	26 390	26 390
7.2	Environment—level 2	7 months	7 659	7 659
7.3	Environment—level 3	4 months	2 979	2 979
7.4	Environment—level 4 (new module)	3 months		1 490
8 Efficacy and safety				
8.1	Efficacy and safety—level 1	6 months	4 740	4 740
8.2	Efficacy and safety—level 2	4 months	1 950	1 950
8.3	Efficacy and safety—level 3	3 months	1 160	1 160
9 Non-food trade		6 months	1 175	1 175
10 Special data				
10.1	Special data—level 1	13 months	nil	nil
10.2	Special data—level 2	7 months	nil	nil
10.3	Special data—level 3	7 months	nil	nil
11 Finalisation				
11.1	Finalisation—type 1	3 months	8 110	8 110
11.2	Finalisation—type 2	2 months	3 090	3 090
11.3	Finalisation—type 3	2 months	1 730	1 730
12 Limits on use of information			460	460

Table 20: Other services' fees from 1 February 2023

Service	Description	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
Certificates of Export			
Certificate of Export	No technical assessment	125	125
Certificate of Export	Requires technical assessment	230	230
Good Manufacturing Practice (GMP) fees			
GMP Licence application	Licence application fee	900	900
GMP Licence application	Assessment fee – Category 1 & multi-category licences	7 500	7 500
GMP Licence application	Assessment fee – Category 2,3 or 4 licences	5 000	5 000
GMP Licence application	Assessment fee – Category 6 licences	1 800	1 800
GMP Annual Licence fee	Category 1 & multi-category licences	7 500	7 500
GMP Annual Licence fee	Category 2,3 or 4 licences	5 000	5 000
GMP Annual Licence fee	Category 6 licence	1 800	1 800
GMP Licence variation	GMP Audit fee (if required)	1 800	1 800
GMP Overseas Manufacture	Annual overseas GMP compliance assessment fee	1 000	1 000
GMP Annual Licence fees – Low value manufacturers (Annual wholesale value of products manufactured is less than $50,000)			
GMP Annual Licence fee	Low value manufacturers – Category 1 & multi-category	3,750	3 750
GMP Annual Licence fee	Low value manufacturers – Categories 2,3 or 4	2 500	2 500
GMP Annual Licence fee	Low value manufacturers – Category 6	900	900
Hormonal Growth Promotant (HGP) fees			

Service	Description	Fee prior to 1 February 2023 ($)	Fee from 1 February 2023 ($)
HGP	Application/renewal fee	429	429

Consequential change to the calculation for the period to conclude a reconsideration:

The modular assessment items are referenced in the meaning of **A** and **B** of the formula under the Code Regulations to work out the period in which the APVMA must conclude a reconsideration of an approval or registration.

Under the existing formula:

A meant the longest of the periods, in months for whichever of previous module items 3.1, 3.2, 3.3, 4.1, 7.1, 7.2, and 7.3 that the APVMA determined was necessary for a reconsideration

B meant the longest of the periods, in months, for whichever of previous module items 2.1 to 2.3, 5.1, 5.2, 5.4, 6.1 to 6.3, 9, and 10.1 to 10.3 that the APVMA determined was necessary for the reconsideration.

The amalgamation of the work health and safety module with the toxicology module to create the new health modules, together with the other new modules set out in Table 19 necessitates some consequential changes to this formula.

The formula will be updated to include the new modules where relevant. For example, the inclusion of new module 3.6 is not necessary as this module will be for 'a new source of an approved active constituent, requiring health consideration of novel impurities' which is not relevant to a reconsideration. The formula will also be amended to ensure the overall period derived from the formula in sub-regulation 78B(5) is maintained despite the merger of the toxicology and work health and safety modules into the new health module.

Cost recovery arrangements for financial year 2022–23

The following table provides a complete summary of the APVMA's cost recovery arrangements for the FY2022–23.

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 21: Registration & approvals – FY2022–23 estimated revenues & costs

Item recoverable service	Est Volume	Fee ($)	Method of cost recovery	Estimated Fee Revenue 2022–23 ($)	Estimated Levy/ Annual Fee Revenue 2022–23 ($)	Estimated Total Cost 2022–23 ($)
Item 1	1	116 501	Fee and Levy	116 501	127 638	244 139
Item 2	10	Modular assessment fee	Fee and Levy	235 318	692 955	928 273
Item 3	–	83 511	Fee and Levy	–	–	–
Item 4	1	44 644	Fee and Levy	44 644	–	44 644
Item 5	34	7 566	Fee and Levy	257 244	297 935	555 179
Item 6	24	6 406	Fee and Levy	153 744	64 882	218 626
Item 7	220	2 632	Fee and Levy	579 040	414 019	993 059
Item 8	154	2 632	Fee and Levy	405 328	71 471	476 799
Item 9	6	2 632	Fee and Levy	15 792	–	15 792
Item 10	197	Modular assessment fee	Fee and Levy	2 697 599	4 264 545	6 962 144
Item 10A	37	Modular assessment fee	Fee	98 286	–	98 286
Item 10B	–	Fee per legislative instrument	Fee	–	–	–
Item 11	4	36 205	Fee and Levy	144 820	–	144 820
Item 12	542	2 018	Fee and Levy	1 093 756	967 585	2 061 341
Item 13	–	–	Registration renewal fee	–	213 306	213 306
Item 13A	378	175	Fee and Levy	66 150	–	66 150
Item 14	260	Modular assessment fee	Fee and Levy	2 001 901	2 405 543	4 407 444
Item 15	–	38 776	Fee and Levy	–	413 212	413 212

Item recoverable service	Est Volume	Fee ($)	Method of cost recovery	Estimated Fee Revenue 2022–23 ($)	Estimated Levy/ Annual Fee Revenue 2022–23 ($)	Estimated Total Cost 2022–23 ($)
Item 16	–	27 031	Fee	–	–	–
Item 17	188	5 442	Fee and Levy	1 023 096	326 968	1 350 064
Item 18	42	4 252	Fee and Levy	178 584	–	178 584
Item 19	36	350	Fee and Levy	12 600	20 317	32 917
Item 20	181	350	Fee and Levy	63 350	561 257	624 607
Item 21	129	350	Fee and Levy	45 150	2 931 810	2 976 960
Item 22	4	–	Registration renewal fee	–	523 871	523 871
Item 23	59	Modular assessment fee	Fee and Levy	229 037	165 274	394 311
Item 24	–	Modular assessment fee	Fee and Levy	–	303 948	303 948
Item 25	10	Modular assessment fee	Fee and Levy	79 864	486 957	566 821
Item 27	13	Modular assessment fee	Fee and Levy	611 396	782 624	1 394 020
8L	287	50	Fee and Levy	14 350	3 633	17 983
8M	2	50	Fee and Levy	100	1 872	1 972
8P	133	50	Fee and Levy	6 650	4 925	11 575
NV	914	50	Fee and Levy	45 700	318 715	364 415
Total registrations and approvals:				**10 220 000**	**16 365 262**	**26 585 262**

Table 22: Other services – FY2022–23 estimated revenues and costs

Item recoverable service	Est Volume	Fee ($)	Method of cost recovery	Estimated Fee Revenue 2022–23 ($)	Estimated Levy/ Annual Fee Revenue 2022–23 ($)	Estimated Total Cost 2022–23 ($)
HGPs Monitoring and Control	152	429	Fee and Levy	65 208	5 155	70 363
GMP Licencing and compliance						
GMP Audit Assessment fee—Item 1 and Multi-Item 2–4	67	7 500	Fee and Levy	502 500	270 126	772 626
GMP Audit Assessment fee—Single Item 2–4	41	5 000	Fee and Levy	205 000	110 201	315 201
GMP Audit Assessment fee—Item 6	66	1 800	Fee and Levy	118 800	63 863	182 663
GMP Foreign Assessment fee	361	1 000	Fee and Levy	361 000	194 061	555 061
GMP Licence Application	10	900	Fee and Levy	9 000	4 838	13 838
GMP Supplement Audit Review	2	1 800	Fee and Levy	3 600	1 935	5 535
Certificates of Export						
Certificate of Export (requires technical assessment)	190	125	Fee and Levy	23 750	69 535	93 285
Certificate of Export (no technical assessment)	140	230	Fee and Levy	32 200	51 237	83 437
Pre-Application Assistance	190	Tiered	Fee and Levy	159 000	1 523 476	1 682 476
Ag Vet Code Requests	221	95	Fee and Levy	20 995	8 535	29 530
Chemical Review			Registration renewal fee		1 523 420	1 523 420
Adverse Experience Reporting Program			Registration renewal fee		428 062	428 062
Assessment, Investigations and Monitoring			Registration renewal fee		1 231 782	1 231 782
Total other services:				**1 501 053**	**5 486 226**	**6 987 279**

Risk assessment

The overall risk rating for the CRIS is medium because the:

- change in annual cost recovery revenue for the regulatory activity is between 5% and 10%
- 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 $40 million.

Risk mitigation

While reviews of cost recovery arrangements are usually required to be undertaken every 5 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.

Stakeholder engagement

The APVMA undertakes targeted consultation with key stakeholders regarding cost recovery. Based on stakeholder feedback, service levels, activity costs and current volumes the APVMA will not be seeking to increase fees from the FY2020–21 CRIS but will be providing additional modules that may reduce the cost and time related to certain applications.

The APVMA held the following stakeholder consultation forums and meetings throughout FY2020–21, FY2021–22 and FY2022–23:

- APVMA Consultative Forum
    - This forum is intended to facilitate engagement between the APVMA and stakeholders in relation to the National Registration Scheme for Agricultural and Veterinary Chemicals and enable transparent communication and information sharing on strategic issues to support effective agvet chemical regulation.
    - The forum has representatives from ten organisations from the agricultural and veterinary chemicals (agvet) sector and meets biannually. The forum met on the following dates during the period:
        - 18 August 2020
        - 9 February 2021
        - 20 August 2021
        - 24 February 2022
        - 3 August 2022
- APVMA Cost Recovery Working Group
    - This working group is intended to facilitate engagement between the APVMA and industry in relation to the APVMA's cost recovery arrangements.
    - Its membership comprises of one representative from the following organisations: APVMA (Chair), Accord Australasia, Animal Medicines Australia, CropLife Australia, National Farmers' Federation, Veterinary Manufacturers and Distributors Association Ltd and Department of Agriculture, Fisheries & Forestry (Observer).
- Discussions at roundtables and board meetings throughout FY2020–21, FY2021–22 and FY2022–23
- Public consultation via the APVMA website from 11 August 2022 to 8 September 2022

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

Financial estimates

Forecast operating results of cost recovery arrangements

The financial estimates in Table 23 show the expenses of the full cost recovery approach, and other activities funded through own source income.

Table 23: Forecast operating results FY2022–23

Budgeted income & expenditure	2022–23 FY Budget
Total industry income	**38 402 000**
Appropriation	1 633 000
Payment from related entities	144 000
Own-source revenue	89 000
Penalties	16 000
Total income	**40 284 000**
Total BAU expenditure	**40 259 000**
Budget: surplus/(deficit) from ordinary operations	**25 000**

Table 24: Industry contribution forecast FY2022–23

Industry Income	2022–23 FY Budget
Levies	19 898 000
Annual renewal fees	6 783 000
Product application fees	8 670 000
Good Manufacturing Practice	1 200 000
Permits, actives, and other fees	
Permit fees (Items 19 to 23)	350 000
Actives (Items 15 to 18)	1 200 000
Pre-application assistance (PAA)	159 000
HGP fees	65 000
Certificates Of Export	56 000

Industry Income	2022–23 FY Budget
Agvet Code Requests	21 000
Total industry income	**38 402 000**

The APVMA's financial reserve

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

To manage this, the APVMA aims to maintain sufficient levels of cash for liquidity (working funds) and financial sustainability (a financial reserve) (which forms part of its equity). Without appropriate level of working funds and this financial reserve, the APVMA would risk periods of time where its liabilities could exceed its assets and result in negative equity.

The financial reserves proposed are in 3 parts:

a) Working funds based on 3 months of operating expenses (working capital). Based on the business-as-usual expenditure this equates to a $10.0 million target.

b) Cash reserve for financial sustainability that is used to offset operating loss in a financial year from a downturn in income receipts. This reserve is maintained at 6% of turn over which is currently equal to $2 million.

c) Capital and operating development reserve that can be used to pay for capital replacements and investment in ongoing efficiency through technology or process improvement.

Performance

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
- measurement and assessment must comply with any requirements prescribed by the rules.

Table 25 shows actual operating results from 2017–18 to 2021–22. The objective is to have a balanced position over the long-term noting that the operating results ranged between deficits to surplus in any one year. The reason for this is due to timing of when income is received, and expenditure incurred.

Table 25: Actual operating results FY2017–18 to FY2021–22

	2017–18 $'000	2018–19 $'000	2019–20 $'000	2020–21 $'000	2021–22 $'000
Expenses	39 908	47 337	41 154	36 385	36 016
Revenue	39 028	57 320	57 465	43 423	43 687
Surplus/(deficit)	**(880)**	**9 983**	**16 311**	**7 038**	**7 671**
Less: Movement of NPP funds and COVID appropriation	–	(12 515)	(14 513)	(1 388)	485
Surplus/(deficit) of costs recovered	**(880)**	**(2 532)**	**1 798**	**5 650**	**8 156**

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. We report our timeframe performance on our website.

The APVMA's self-assessment against key performance indicators (KPIs) is detailed in our Annual Report 2021–22.

CRIS approval and change register

The CRIS approval and change register is captured in Table 26 and details the dates, basis, and approver for changes to the CRIS.

Table 26: 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
22/05/2022	CRIS financial update for FY2020-21	CEO APVMA	Annual update
19/10/2022	Agreement to the CRIS	Minister for Agriculture, Fisheries and Forestry	Approval to change the module structure and fees from 1 February 2023

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Appendix

Glossary

Term	Description
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*
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 3 broad Items: • Fees for goods and services • Cost recovery' taxes (primarily levies, but also some excises and customs duties).
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, 3 to 4 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.

Term	Description
DAFF	Australian Government Department of Agriculture, Fisheries & Forestry
GMP	Good Manufacturing Practice
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
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
Vet	Veterinary