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 year

1 October 2025 to 1 October 2026

Charging for regulatory activity involves government entities charging individuals or organisations in the non-government sector some or all of the minimum efficient costs of a specific government activity. The Cost Recovery Policy along with the Australian Government Charging Framework (the Charging Framework) sets out the policy under which government entities design, implement and review charging for regulatory activities. The CRIS is the public document to ensure the transparency and accountability for the level of the charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

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1. Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemicals proposed for supply and use in Australia.

Before agvet chemical products can be sold, supplied, or used in Australia, they must be evaluated and registered or authorised under a permit issued by the APVMA – unless exempt by the Agvet Code. This regulates agvet chemicals to manage the risks of pests and diseases for the Australian community, and to protect Australia's trade and the health and safety of people, animals, and the environment

1.1 Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the APVMA implements cost recovery for the assessment, registration and regulation of agvet chemicals in Australia. It reports financial and non-financial performance information for the regulation of the agvet chemicals industry and contains financial forecasts for 2025-26 and three forward years. The APVMA will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

The agvet chemical industry is the primary stakeholder in the agvet regulatory process. Without regulatory approval, the industry cannot manufacture or supply agvet chemicals for use in Australia. Therefore, under the Australian Government Charging Framework (Charging Framework), the Australian Government has determined that it is appropriate for the industry to bear the efficient costs of the regulatory functions delivered by the APVMA.

Current policy requires the APVMA to fully recover its operational costs through a mix of fees, charges, and levies imposed on the industry it regulates. Operational costs are incurred by the APVMA in undertaking registration assessments, renewing and reviewing existing product registrations, and performing compliance, monitoring, and enforcement activities to ensure the industry's integrity.

Functions and powers

Australians expect agvet chemicals in the marketplace to be safe, of high quality, and comparable to international standards. The APVMA protects the health and safety of the community, animals, and the environment by regulating the sale of agvet chemicals for safety, efficacy, and potential impacts on trade. The APVMA delivers efficient, best practice regulatory outcomes through collaboration by assessing products based on a rigorous scientific evaluation of risks.

The regulatory functions of the APVMA are:

- **Pre-market Assessment and Registration**: Evaluating and approving active constituents and registering chemical products before they enter the market.
- **Post-market Monitoring and Enforcement**: Ensuring ongoing compliance with the legislation through continuous oversight.
- **Licensing and Auditing Veterinary Medicine Manufacturers**: Ensuring both Australian and international veterinary medicine manufacturers adhere to stringent standards.

Agvet chemical products are divided into 2 main categories and one minor category:

- Agricultural chemicals and veterinary medicines.
- The minor category of pool chemicals.

All such products must be registered with the APVMA, or authorised under permit, before they can be manufactured, supplied, or used in Australia. Active constituents of chemical products must also be approved by the APVMA.

If a problem is identified with a registered chemical product, active constituent, or manufacturer, the APVMA can take regulatory action, ranging from continued monitoring to withdrawal of the product or active constituent from the market and, in the case of veterinary medicines, revocation of manufacturing licenses.

Frequency

The guidelines require an annual review of the CRIS. The APVMA will align with those requirements to conduct an annual review of the CRIS after 2025-26, with an annual review to be completed for implementation by 1 October each year.

2. Policy and statutory authority to charge (cost recover)

The Australian Government's policy and statutory framework sets the cost recovery of regulatory activities by the APVMA. The APVMA applies the government's cost recovery policy to charge non-government recipients for specific regulatory activities. This includes fees for registration and approval of agvet chemicals, with the remaining costs covered by statutory levies on the sales of registered products.

2.1. Government policy approval to charge for this regulatory activity

The APVMA is a corporate Commonwealth Entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). The Finance Minister has made a government policy order in *Public Governance, Performance and Accountability (Charging for Regulatory Activities) Order 2017*, that the APVMA must apply the Charging Framework and the Australian Government Cost Recovery Policy (Cost Recovery Policy) as a full cost recovered agency.

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 efficient costs of those activities. The Cost Recovery Policy aims to promote consistent, transparent, and accountable charging for government activities and supports the proper use of public resources.

The Prime Minister granted the policy approval 13 December 2019 to partially cost recover the APVMA's fee-for-service regulatory activities at an average of 40 per cent, with the balance of regulatory costs to be 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.

2.2. Statutory authority to charge

The APVMA was established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) and operates as an independent statutory authority of the Commonwealth. It administers the National Registration Scheme for Agricultural and Veterinary Chemicals in partnership with state and territory governments.

The APVMA imposes regulatory charges under the authority of the following legislation:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act)
- *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code)
- *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*

These acts, along with their respective regulations, provide the legal framework for the APVMA to charge fees and levies related to its regulatory activities.

2.2.1. Functions of the APVMA

The functions of the APVMA, as set out in section 7 of the Administration Act, include:

- assessing the suitability of active constituents, chemical products, and their labels for sale in Australia
- providing information and cooperating with Commonwealth, state, and territory governments on chemical management
- keeping records and statistics of approvals, registrations, permits, and licenses
- evaluating the effects of chemical product use
- developing codes of practice, standards, and guidelines for chemical products in cooperation with governments
- disseminating information on chemical products and their use
- facilitating the application of evaluation and testing results
- exchanging information with international bodies
- reporting and advising the Minister on matters relating to chemical products
- promoting uniform national procedures for chemical control.

2.2.2. Fee structure

The APVMA's fee structure is authorised by several provisions in various pieces of legislation related to agvet chemicals. These include:

- **Application and registration renewal fees:** Provided for in the *Agricultural and Veterinary Chemicals Code Regulations 1995*, under the *Agricultural and Veterinary Chemicals Code Act 1994*.
- **Manufacturers' Licensing Scheme ('MLS') fees**: Covered by the Agvet Code Regulations
- **Levies**: Payable on sales or disposals of agvet chemical products, authorised by the Agricultural and *Veterinary Chemical Products (Collection of Levy) Act 1994* and associated regulations
- **Good Manufacturing Practice ('GMP') Audit Assessment Fees**: Charged pursuant to subsection 164(1) of the Agvet Code and relevant regulations
- **Export certificates**: Fees provided for in the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995.*

3. Cost Recovery Model

Historically, the APVMA has relied upon excel-based Activity-Based Costing (ABC) calculations for cost allocation, but the complexity of APVMA data sources and the basis of calculations required significant effort to manage and resulted in limited transparency. A need to implement an efficient, transparent, and effective ABC approach led the APVMA to transition to a modern business intelligence tool, to integrate and automate the approach to ABC.

From 2022 to 2024 the Department of Finance oversaw the APVMA's transition to a modernised ABC over a period of 9 months. The updated APVMA cost recovery approach is an ABC that meets the requirements of the Australian Government Charging Framework (Charging Framework). The new model has been used to identify the cost of activities detailed in this CRIS.

3.1. Cost recovery charges

The characteristics of the APVMA's activities determine the type of cost recovery charge used. The cost recovery charges applied by the APVMA are:

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 Taxation Act. It differs from general taxation as it is 'earmarked' to fund activities provided to the group that pays the levy.

In addition, the APVMA charges a fee annually for the renewal of a product's registration.

3.2. 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

Some APVMA functions result in 'outputs' that may be considered essential for robust post-market regulation but do not directly benefit individual applicants. These include:

- Chemical review
- Assessment, Investigations and Monitoring
- Adverse Experience Reporting (AERP) and Hormonal Growth Promotant (HGP)

The APVMA also manages the Manufacturer's Licensing Scheme (MLS) that licenses manufacturers of veterinary chemical products and audits their compliance with the Australian code of good manufacturing practice for veterinary chemical products (GMP Code). These activities are partially funded by fees paid by applicants, as the

services provide them with exclusive commercial benefits. Additionally, the APVMA issues permits that authorise the importation of unregistered products and unapproved active constituents and certificates of export for agricultural and veterinary chemicals.

Table 1 summarises the classification of the APVMA's regulatory charging activities as pre and post market regulatory functions, and information and governance.

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)
		Variations to existing registered products, approved active constituents, or approved labels.
		Applications for technical assessment
		Consents to Import
		Certificates of Export
		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
		Recalls
	Investigation and enforcement	Compliance and enforcement
Information and governance	Information and governance activities	APVMA Governance and policy
		Corporate publications
		Informing policy
		Parliamentary
		Presentations and seminars
		Senate Estimates
		Website

3.2.1. Registration and approvals

Anyone intending to supply and/or sell agvet chemicals in Australia must first obtain APVMA approval for active constituents, registration of chemical products, and approval of associated labels.

The APVMA grants registration if the evaluation of a product has shown that it meets the statutory criteria for safety, trade, and efficacy, or complies with an established standard. The evaluation also must demonstrate that the product label contains adequate instructions for safe and effective use. In approving an active constituent, the APVMA must be satisfied that it meets the statutory safety criteria.

Applicants are required to apply for approval and registration under the APVMA application framework which itemises the applications provided in the Agvet Code. The item numbers listed in the Regulations represent different types of regulatory submissions with each item having a distinct assessment period and fee so that the cost of applications generally reflects the complexity and size of the application.

Table 2 provides a detailed description of each of the current Items and their assessment periods.

Table 2: Application Item descriptions

Item	Description of application	Assessment period
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
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 assessment of the active constituent and chemical product	Modular assessment period
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
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	18 months

Item	Description of application	Assessment period
	(d) poison schedule classification is required	
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

Item	Description of application	Assessment period
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 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
Item 7	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:	3 months

Item	Description of application	Assessment period
	(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	
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 (d) the chemical product is to be registered with a different name	3 months
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
Item 10	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 and approval of the active constituent in the chemical product; or	Modular assessment period

Item	Description of application	Assessment period
	(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
Item 10B	Application under subsection 14C(1), 14D(1) or 14E(1) of the Code	
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
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
Item 13	Application to vary relevant particulars or conditions of registration or label approval if:	3 months

Item	Description of application	Assessment period
	(a) the variation is to allow a minor change; and (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA	
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 month
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
Item 15	Application for approval of an active constituent requiring a full assessment	14 months
Item 16	Application for approval of an active constituent requiring less than full assessment but requiring a toxicological assessment	9 months
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
Item 18	Application to vary relevant particulars or conditions of an approved active constituent	7 months

Item	Description of application	Assessment period
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
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
Item 21	Application for a permit, or extension of a permit, where the proposed use is a minor use	Modular assessment period
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
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
Item 24(a)	Application made under section 10 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 1 to 10, 15, 16 or 17)	Modular assessment period
Item 24(b)	Application made under section 27 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 11 to 14 or 18	Modular assessment period

Item	Description of application	Assessment period
Item 25	Application made under regulation 8AS for a technical assessment	Modular assessment period
Item 27	Timeshift application (see regulation 3BA)	Modular assessment period
Item 28	Application made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination.	Modular assessment period
Item 29	Application made under regulation 19AEB to make an interchangeable constituent determination	Modular assessment period

Table 3 outlines the registration and approval cost recovery mechanisms for Items

Table 3: Application Items and cost recovery mechanisms

Type of application		Current Item List	Cost recovery mechanism
Chemical Product applications	New product registrations	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A,	Approximately 40% of costs are recovered by fees with the remaining funded by levies.
	Variations to registered products	12	
		13	There is currently no charge for this application Item. The cost of processing these applications is funded by registration renewal fees.
		13A	Currently a nominal fee is charged for these application Items with the remaining costs funded by levies.
		11, 14	Approximately 40% of costs recovered by fees with the remaining funded by levies.
Active applications		15, 16, 17, 24(a)	
		18, 24(b)	
Permit applications		19, 20, 21	Nominal fees are charged for these application Items with the remaining costs funded by levies.
		22	No fee is charged 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	
Time shift applications		27	
Ingredient determination		28	
Interchangeable constituent determination		29	

Items 1 to 14 (product applications)

Items 1 to 12 and 14 are application streams related to sections 10 and 27 of the *Code Act*. Applications under section 10 involve the approval of an active constituent for a proposed or existing chemical product, the registration of a chemical product, or the approval of a label for containers of a chemical product. Applications under section 27 pertain to the variation of relevant particulars or conditions associated with an approved active constituent, a registered chemical product, or an approved label for a chemical product.

Items 15 to 18 (active constituent applications)

Current Items 15 to 18 pertain to active constituents. Items 15, 16 and 17 address applications for the approval of new active constituents, including new sources of active constituents. Item 18 deals with variations to an approved active constituent.

Items 19 to 23 (permit applications)

Items 19 - 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.

Item 20 - A permit, or extension of a permit, where a previous assessment remains valid, and no data of a technical nature is required.

Item 21 - A permit that covers applications for minor use, which are issued for the use of agvet chemicals in small, emerging, or niche industries where an insufficient economic return exists for a registrant to pursue product registration.

Item 22 – A permit applications seeking emergency use permits in situations where the proposed use is unforeseen, such as the outbreak of an exotic pest or disease, or unusual weather patterns causing higher or more frequent pest or disease incursions.

Item 23 is for applications seeking research permits, allowing the use of agvet chemicals in technical trials to generate information supporting potential applications for registration or permits. Since the information generated from research under these permits can later be used to obtain registration (enabling the registrant to recoup application fees through product sales and attract data protection), applicants should be charged for the cost of assessment. However, they will not be charged twice for the same assessment when a formal application for registration is lodged.

Permit application fees are exempt for Australian, state, or territory governments when the permit supports their core business. Activities that are not exempt from fees include those that yield a profit from investment, or services provided. This would include activities such as:

- commercial
- state forestry operations
- research activities 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)

Items 24 and 25 cover assessments not included in Items 1 to 23 or 27 to 29. Currently, Item 24 pertains to other applications made under section 10 (approval and registration applications) and section 27 (variations).

Item 25 pertains to applications for technical assessments under regulation 8AS.

Item 27 (timeshift application)

A timeshift application provides for the staged submission of supporting data packages allowing assessments to commence where all information is available, while other supporting data packages (which may include efficacy and crop safety, environment and residues and trade) are being completed. The application is assessed according to a project plan which is developed and agreed between the applicant and the APVMA, and which can be amended by mutual agreement.

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) 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.

3.2.2. Pre-application assistance (for registrations, approvals and permits)

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

PAA is offered on a fee-for-service basis; the fees are prescribed in the *Agricultural and Veterinary Chemicals Code Regulations (Pre-application Assistance Fee) Instrument 2015*. The fees charged for PAA directly relate to the complexity and effort required and are currently divided into three tiers.

In many cases, if a PAA fee was paid in relation to a proposed product application, the product application fee for a subsequent submission is reduced by an amount prescribed in the Agvet Code Regulations.

3.2.3. Consents to Import

A person must not import an unregistered agvet product or unapproved active constituent into Australia unless it has either been exempted from the importation provisions or the importer has obtained written consent from the APVMA[1]. 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.

Charging a fee for consents to import will act as a disincentive to the lodgement of applications and this will be inconsistent with policy goals. Accordingly, no fee is charged for this service. The costs of Consent to Import activities are funded by product registration renewal fees.

3.2.4. Certificates of Export

Before accepting exports of an agvet product from Australia, many countries require assurance from the APVMA that the exported chemical is suitable for supply and use. Under Section 69D of the Administration Act the APVMA has the legislative authority to issue a Certificate of Export for an agvet product.

Individuals seeking this certificate are charged a direct fee for the service, with any remaining costs recovered through APVMA levies.

3.3. Monitoring ongoing compliance with legislation

Monitoring ongoing compliance with the legislation focuses on ensuring registered products and manufacturers continue to comply with regulatory standards after initial registration/approval. The APVMA conducts regular monitoring audits to maintain the integrity of the regulatory framework.

3.3.1. Good Manufacturing Practice (GMP)

Veterinary chemical products manufactured in Australia must be manufactured in premises that are compliant with the Code of Good Manufacturing Practice (‘GMP’). This does not apply to agricultural chemical products.

GMP compliance is assessed for Australian manufacturers through the Manufacturing Quality and Licensing (‘MQL’) 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.

GMP fees have not been reviewed since 2015 and, as a result, to impose full cost recovery in this CRIS is too onerous for industry. The APVMA proposes to partially recover in this CRIS with the intent to move to full cost recovery over the next couple of years.

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

3.3.2. Hormonal Growth Promotant Scheme

The APVMA is responsible for controlling the supply of Hormonal Growth Promotants ('HGP's') within the National HGP Control and Monitoring System managed by the Department of Agriculture, Fisheries and Forestry (DAFF). 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.

The HGP scheme is funded by a direct fee charged to users of the service.

3.3.3. Adverse Experience Reporting Program

The AERP is the primary mechanism for the APVMA to receive and consider stakeholder and public feedback on adverse experiences relating to the use of agvet chemicals post-registration.

The full cost of the AERP is recovered from registration renewal fees and APVMA levies.

3.3.4. 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.

The full cost of the program is recovered from registration renewal fees and levies. The cost of chemical review is anticipated to increase with a proposed increase in the scope of the program.

3.4. 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.

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

3.4.1. 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, as a portfolio agency of DAFF, also contributes to and assists in policy development and undertakes parliamentary servicing functions including:

- attending Senate Estimates hearings
- responding to Questions on Notice
- ministerial briefings.

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

3.4.2. APVMA enabling activities

APVMA enabling activities are business processes that relate to the whole of the APVMA and are generally associated with indirect costs. 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 and stakeholder engagement
- Records and knowledge management
- Policy support

APVMA enabling activities support the delivery of services to individuals, organisations, and the agvet industry, as well as in performing other regulatory tasks. These activities incur costs that are not directly linked to specific services or regulatory actions for particular individuals or organisations and are thus considered indirect costs.

3.5. Costs of the regulatory activity

Section 3.5 provides a detailed overview of the costs associated with the APVMA's regulatory charging activities. Understanding these costs is crucial for ensuring transparency, accountability, and efficiency in the APVMA’s operations. The cost model outlines the methodology used to calculate costs, the cost components involved, and the costs associated with different regulatory functions, including registrations and approvals, monitoring ongoing compliance, investigations and enforcement, and information and governance activities.

3.5.1. Costing methodology

The APVMA uses Activity Based Costing ('ABC') methodology to calculate the costs for all regulatory activities. Actual costs, as recorded in the finance system, are associated with specific cost groups aligned with the type of regulatory activity or business operation delivered. This approach ensures that costs are assigned to the correct cost pool, limiting the risk of cross-subsidisation between regulatory activities and preventing understated or overstated costs. Salaries and employee-related expenses make up approximately 64% of total expenses for the APVMA. The APVMA ABC model was developed based on historical data up to the end of the financial year 2022-23.

Cost Pools

All costs are allocated to cost pools based on cost centre delivery functions (business units) relying on data from the finance system. Overhead costs are distributed across these pools using headcount and expenditure as cost drivers. Figure 1 illustrates the high-level process of establishing cost pools and Figure 2 illustrates the allocation of cost pools.

Figure 1 Process to establish cost pools

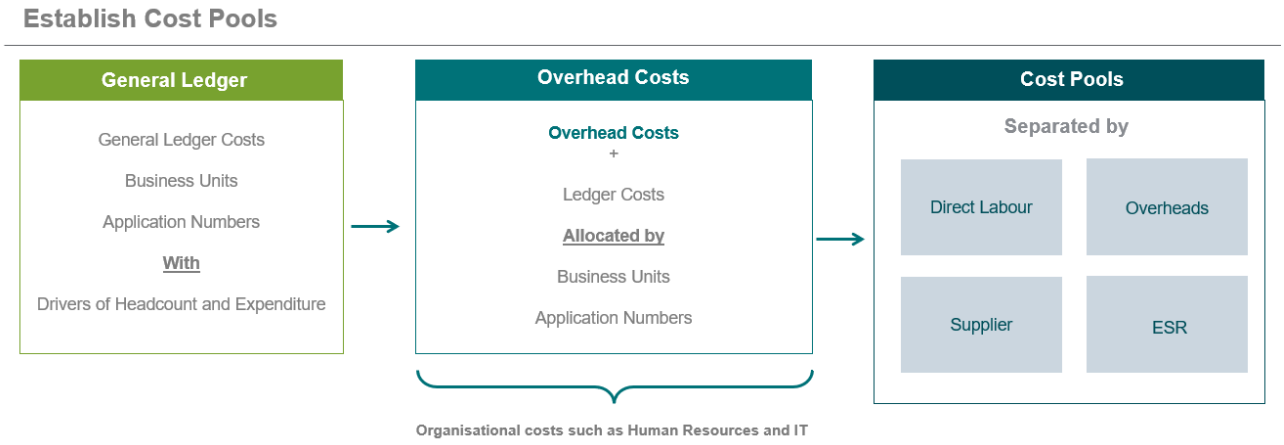
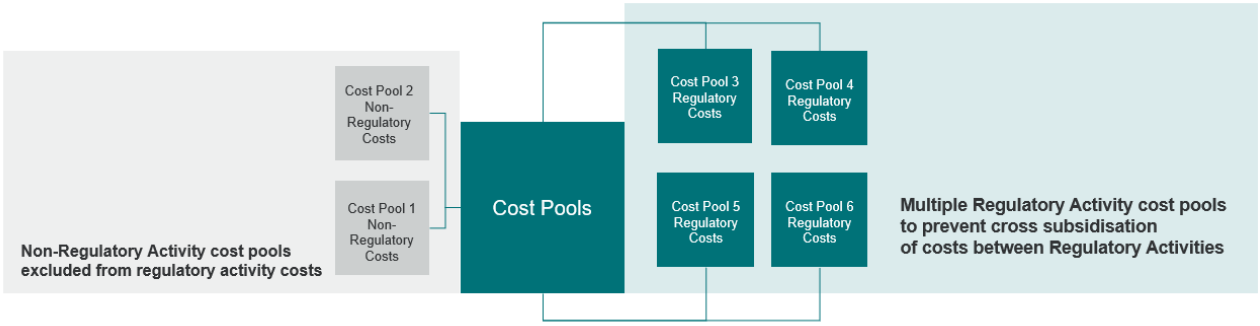


Figure 2 Overview of cost pool segregation



Cost Objects (Items)

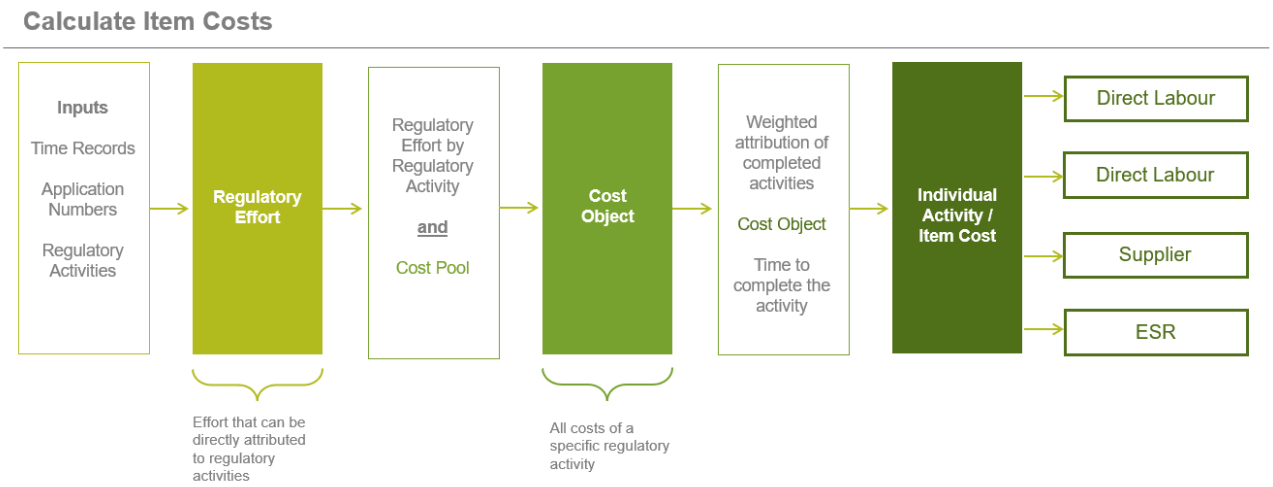
Costs are allocated to specific items and regulatory activities (cost objects) through the identification of costs and application of direct and indirect cost drivers:

- **Direct labour**: Labour costs are allocated based on employee timesheets, finance system records, and application data.
- **Direct suppliers**: Contractors, consultants and legal costs are allocated directly to items based on application and finance system data.
- **Overheads:** Remaining costs, including overheads, are allocated to items using expenditure allocated at that point as the driver, ensuring that the effort influences the cost driver.

Individual Item costs

The delivery of Items spans multiple financial years, as such a straight division of total costs by new applications or completed applications would not reflect the true individual Item cost. An analysis was conducted to identify the average duration for Item completion, and costs were attributed based on a weighted approach to applications worked on during the period. This ensures a reasonable and accurate distribution of costs to each regulatory activity. Figure 3 illustrates the process of calculating Item costs.

Figure 3: Process to calculate Item cost



3.5.2. Cost components

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

- 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 to an activity, 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 in section 0 detail the total cost per service by direct and indirect components. The costs reported are based on the results from the ABC model.

3.5.3. 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. The Australian Government and the states and territory governments, as part of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), agreed that the costs of assessing applications should be collected in 2 parts:

1. forty percent of the assessment costs being charged as an upfront application fee
2. the balance of revenue required to fund the activity recovered by levies.

The policy intends to enable the establishment of an application fee to assess and register new and innovative products that is at a level so as not a disincentive bringing new products to the market, particularly for small businesses, niche products, and chemical products that have a low value of sales.

The 2025-26 estimated total costs of registration and approvals outputs are shown in Table 4.

Table 4: Cost components of registration and approvals

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Employee expenses	Technical and administrative assessment costs	Direct Cost	18,145,051
Suppliers	Outsourced activities including scientific assessment services undertaken by external entities	Direct Cost	1,486,066
Overheads		Indirect Cost	12,038,754
Total			**31,669,871**

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

The 2025-26 estimated costs for Pre-application assistance ('PAA') activities are shown below in Table 5.

Table 5: Cost components of PAA

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Employee expenses	Technical and administrative assessment costs	Direct Cost	1,066,897
Suppliers	Outsourced activities	Direct Cost	44,322
Overheads		Indirect Cost	497,720
Total			**1,608,939**

Consents to Import

The 2025-26 estimated costs for Consents to Import are shown in Table 6.

Table 6: Cost components of Consents to Import

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Service: Consents to Import			
Employee expenses	Assessment and administrative services	Direct Cost	1,950
Suppliers	Outsourced activities	Direct Cost	77
Overheads		Indirect Cost	2,527
Total			**4,554**

Certificates of Export

The 2025-26 estimated costs for Certificates of Export are shown in Table 7.

Table 7: Cost components of Certificates of Export

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Service: Certificates of Export			
Employee expenses	Assessment and administrative services	Direct Cost	171,640
Suppliers	Outsourced activities	Direct Cost	6,744
Overheads		Indirect Cost	44,214
Total			**222,598**

3.5.4. Monitoring ongoing compliance with regulations

Good Manufacturing Practice

The 2025-26 estimated costs of the GMP compliance assessment schemes are shown in Table 8.

Table 8: Cost components of GMP compliance assessment

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Employee expenses	Assessment of MLS licences and imported products for GMP compliance; and management of GMP auditing	Direct Cost	1,398,587
Suppliers	Outsourced activities	Direct Cost	33,256
Overheads		Indirect Cost	1,506,616
Total			**2,938,459**

Hormonal Growth Promotant Scheme

The 2025-26 estimated costs for the HGP Scheme are shown in Table 9.

Table 9: Cost components of the HGP Scheme

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Employee expenses	Assessment of new licences, licence renewals, licence withdrawals and HGP audits (including investigations)	Direct Cost	275,493
Suppliers	Outsourced activities	Direct Cost	23,365
Overheads		Indirect Cost	77,855
Total			**376,713**

Adverse Experience Reporting Program (AERP) and Chemical Review Program

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

The 2025-26 estimated costs for the AERP are shown in Table 10 and Chemical Review in Table 11.

Table 10: Cost components of the AERP

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Employee expenses	Review work	Direct Cost	744,279
Suppliers	Outsourced activities	Direct Cost	63,124
Overheads		Indirect Cost	284,579
Total			**1,091,982**

Table 11: Cost components of the Chemical Review Program

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Employee expenses	Review work	Direct Cost	1,191,316
Suppliers	Outsourced activities	Direct Cost	-
Overheads		Indirect Cost	636,314
Total			**1 827 630**

3.5.5. Investigation and enforcement

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

The 2025-26 estimated costs for investigation and enforcement are shown in Table 12.

Table 12: Cost components of investigation and enforcement

Expense	Inclusions	Attribution	2025-26 Estimated cost ($)
Employee expenses	Non-compliance report processing, product recalls and investigations	Direct cost	1,328,851
Suppliers	Outsourced activities	Direct Cost	112,703
Overheads		Indirect cost	1,686,373
Total			**3,127,927**

3.5.6. Information and governance activities

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

The costs of these activities are recovered as overhead and represented in Table 4 to 15 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.

3.6. Design of regulatory charges

Section 3.6 provides an overview of the current state of cost recovery within the APVMA, detailing the existing approaches and their implications accompanied by a detailed comparison of the fee structures. This comparison aims to highlight the potential benefits and implications of the proposed changes to cost recovery arrangements.

3.6.1. Cost recovery of 40% fee-for-service policy approval

The policy intent underpinning the 40% recovery of application costs, is to ensure that the application fee to assess and register new and innovative products does not act as a disincentive to applicants bringing new products to the market. This is particularly relevant for small businesses, niche products and chemical products that have a low value of sales.

Charging 40% of the application costs accords with the policy approval reaffirmed by the government in November 2019. This lower fee structure encourages more applications for registrations and approvals.

By combining fees with levies, the APVMA creates a more diversified revenue stream, potentially smoothing out the impact of year-to-year fluctuations in application volumes. Additionally, maintaining a partial cost recovery by fees approach aligns better with stakeholder expectations. This approach encourages innovation by lowering cost barriers.

This approach relies on levy income, which can fluctuate and create financial sustainability challenges if levy revenue declines.

3.6.2. Fees

Registration and application fees

Table 13 provides a complete listing of the APVMA's registration and application fees for the existing item numbers. The cost of these items assumes they are recovered at 40% by fees with the remainder recovered from levies in line with the policy intent under the NRA with the exception of items 13 and 13A and items 19 to 21.

Items 19 to 21 historically have been charged at a nominal fee which has not changed since 2015. The APVMA has elected to continue with setting a fee below what would be 40% of the item's cost.

Table 13: Registration and application fees from 1 October 2025

Item	Fee prior to 30 September 2025 ($)	Fee from 1 October 2025 ($)	Estimated Cost ($)
Item 1	116,501	116,501	532,467
Item 2	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 3	83,511	83,511	251,055
Item 4	44,644	44,644	134,490
Item 5	7,566	7,566	16,225
Item 6	6,406	6,406	17,411
Item 7	2,632	2,632	5,981
Item 8	2,632	2,632	5,201
Item 9	2,632	2,632	2,678
Item 10	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 10A	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 11	36,205	36,205	228,542
Item 12	2,018	2,018	5,744
Item 13[2]	Nil fee	Nil fee	3,242
Item 13A[3]	175	175	179

[2] Item is outside the 40/60 policy and recovered from the product registration renewal fee.

[3] Item is outside the 40/60 policy and fee is set at a nominal rate.

Item	Fee prior to 30 September 2025 ($)	Fee from 1 October 2025 ($)	Estimated Cost ($)
Item 14	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 15	38,776	38,776	236,205
Item 16	27,031	27,031	64,866
Item 17	5,442	5,442	5,577
Item 18	4,252	4,252	4,564
Item 19	350	350	633
Item 20	350	350	1,882
Item 21	350	350	22,924
Item 22	Nil fee	Nil fee	9,503
Item 23	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 24(a)	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 24(b)	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 25	Modular assessment fee, plus GST	Modular assessment fee, plus GST	Modular assessment fee, plus GST
Item 27	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 28	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 29	Modular assessment fee	Modular assessment fee	Modular assessment fee
Section 8L	50	50	71
Section 8M	50	50	143
Section 8P	50	50	48
Notifiable Variations	50	50	588

Module fees

Table 14 provides a complete listing of the APVMA's revised module fees from 1 October 2025, identifying the fees applicable.

The minimum fee is equivalent to the fee of module 1 preliminary assessment, unless the total application fee is less, in which case the fee is the lessor amount.

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

Table 14: Module fees from 1 October 2025

Module	Module, level, or type	Period for completion	Fee prior to 30 September 2025 ($)	Fee from 1 October 2025 ($)	Estimated Cost
1 Preliminary assessment		n/a	902	902	2,652
2 Chemistry					
2.1	Chemistry—level 1	13 months	11,074	11,074	43,296
2.2	Chemistry—level 2	9 months	3,075	3,075	12,628
2.3	Chemistry—level 3	6 months	1,954	1,954	5,863
2.4	Chemistry—level 4	3 months	970	970	2,706
2.5	Chemistry—level 5	2 months	480	480	1,353
3 Health					
3.1	Health—level 1	13 months	36,740	36,740	150,784
3.2	Health—level 2	11 months	27,920	27,920	96,513
3.3	Health—level 3	9 months	18,980	18,980	50,512
3.4	Health—level 4	5 months	7,963	7,963	21,197
3.5	Health—level 5	4 months	4,000	4,000	10,102
3.6	Health—level 6	2 months	2,000	2,000	5,051
4. Poison schedule classification					
4.1	Poison schedule classification	13 months	2,435	2,435	7,216
5 Residues					
5.1	Residues—level 1	13 months	25,650	25,650	60,794

Module	Module, level, or type	Period for completion	Fee prior to 30 September 2025 ($)	Fee from 1 October 2025 ($)	Estimated Cost
5.2	Residues—level 2	8 months	11,149	11,149	26,428
5.3	Residues—level 3	6 months	9,000	9,000	21,310
5.4	Residues—level 4	4 months	7,465	7,465	17,679
5.5	Residues—level 5	3 months	2,000	2,000	4,735
7 Environment					
7.1	Environment—level 1	13 months	26,390	26,390	89,929
7.2	Environment—level 2	7 months	7,659	7,659	26,158
7.3	Environment—level 3	4 months	2,979	2,979	10,147
7.4	Environment—level 4	3 months	1,490	1,490	4,298
8 Efficacy and safety					
8.1	Efficacy and safety—level 1	6 months	4,740	4,740	17,589
8.2	Efficacy and safety—level 2	4 months	1,950	1,950	7,261
8.3	Efficacy and safety—level 3	3 months	1 ,160	1 ,160	3,401
9 Non-food trade		6 months	1,175	1,175	1,371
11 Finalisation					
11.1	Finalisation—type 1	3 months	8,110	8,110	30,036
11.2	Finalisation—type 2	2 months	3,090	3,090	7,396
11.3	Finalisation—type 3	2 months	1,730	1,730	4,059
12 Limits on use of information			460	460	4,059

Revised other services fees

Table 15 provides a complete listing of the APVMA's revised fees for other services from 1 October 2025, identifying the applicable fees.

Table 15: Other services fees from 1 October 2025

Service	Description	Fee prior to 30 September 2025 ($)	Fee from 1 October 2025 ($)	Estimated Cost ($)
Good Manufacturing Practice (GMP) fees				
GMP Licence application	Licence application fee	900	900	2,575
GMP Annual Licence fee	Category 1 licences	7,500	7,500	21,575
GMP Annual Licence fee	Category 2,3 or 4 licences	5,000	5,000	13,800
GMP Annual Licence fee	Category 6 licence	1,800	1,800	5,075
GMP Annual Licence fee	Multi-category licences	7,500	7,500	20,600
GMP Annual Licence fee	Low value manufacturers – Category 1	3,750	3,750	10,790
GMP Annual Licence fee	Low value manufacturers – Categories 2,3 or 4	2,500	2,500	6,900
GMP Annual Licence fee	Low value manufacturers – Category 6	900	900	2,540
GMP Annual Licence fee	Low value manufacturers – Multi-category	3,750	3,750	10,300
GMP Licence variation	GMP Audit fee (if required)	1,800	1,800	5,075
GMP Overseas Manufacture	Annual overseas GMP compliance assessment fee	1,000	1,000	2,850
Hormonal Growth Promotant (HGP) fees				
HGP	Application/renewal fee	429	429	2,500
Certificate of Export	No technical assessment	125	125	675
Certificate of Export	Requires technical assessment	230	230	780
Agvet code requests Includes all requests under sub-regulation 73(1) of the Agvet Code Regulations. The hourly fee applies to the rates set out in paragraph 73(2)(a)		$95 per hour	$95 per hour	$788 per hour

Service	Description	Fee prior to 30 September 2025 ($)	Fee from 1 October 2025 ($)	Estimated Cost ($)
	and (b) of the Agvet Code Regulations. There are no changes to the copy and transcript rates set out in out in paragraph 73(2)(c)-(e) of the Agvet Code Regulations.			
Late application fee for renewal of registration		50	50	Not determined
Minimum application fee (sub-regulation 70(6) of the Agvet Code Regulations)		710	710	Not determined
Fee for converting information and documents into electronic form		$90 per hour	$90 per hour	Not determined

Revised PAA fees

At the introduction of PAA the cost and associated fee were based on best estimates. The fees from 1 October 2025 are based on actuals considering the growth in the use and complexity of this activity.

Table 16 provides a complete listing of the APVMA's revised fees for PAA from 1 October 2025.

Table 16: PAA fees from 1 October 2025

Service	Description	Fee prior to 30 September 2025 ($ including GST)	Fee from 1 October 2025 ($ including GST)	Estimated Cost ($ including GST)
PAA Tier 1				
Administration fee	1-unit fee	192.50	192.50	1,828.75
Written response, including research	2-unit fee	385.00	385.00	3,657.50
Meeting with applicant	2-unit fee	385.00	385.00	3,657.50
PAA Tier 2				
Administration fee	1-unit fee	192.50	192.50	1,828.75
Written response, including research	4-unit fee	770.00	770.00	7,315.00
Meeting with applicant	2-unit fee	385.00	385.00	3,657.50
PAA Tier 3				
Administration fee	1-unit fee	192.50	192.50	1,828.75
Written response, including analysis	6-unit fee	1,155.00	1,155.00	10,972.50
Meeting with applicant	2-unit fee	385.00	385.00	3,657.50

3.6.3. PAA (for products, active constituents, and permits)

The full cost of the activity is partially recovered from the PAA application fee, and the bulk of the cost is recovered by levy. A rebate is provided if the applicant proceeds to lodge an application, with the maximum rebate varying according to the Item of the application, as set out in Table 17.

The rebate is provided in recognition that the PAA improves the quality of applications, thereby improving the efficiency of the evaluation process. Rebates are determined according to the complexity of advice needed for specific Items.

Details of applicable rebates are provided in Table 17.

Table 17: PAA – rebates payable from 1 October 2025

Current Item List	Maximum rebate prior to 30 September 2025 ($)	Maximum rebate from 1 October 2025 ($)
1, 2 15, 27	1,400	1,400
3, 4, 11	1,050	1,050
5, 6, 16, 17, 18	700	700
7, 8, 9, 10, 10A, 12, 14, 23, 24(a) & (b)	350	350
19, 20, 21	**350**	**350**
13, 13A, 22, 25, 28, 29	**Nil**	**Nil**

3.6.4. Consents to Import

The costs of Consent to Import activities are funded by product registration renewal fees. As such, no fee is charged for this service.

3.6.5. Certificates of Export

The full cost of this activity is partially covered by a fee from the applicant, with the remaining cost being recovered through levies.

3.6.6. Good Manufacturing Practice

Costs for the MLS have been under-recovered annually, with the difference funded through levies. Historically APVMA's intention was to fully recover costs entirely from a fee.

3.6.7. Hormonal Growth Promotant scheme

Costs for the HGP have been under-recovered annually, with the difference funded through levies under current policy. It is intended that HGP expenses are fully recovered by fees.

3.6.8. Levy rates

Levies, collected on the basis of wholesale value of chemical products sold, are imposed under the following legislation:

- the *Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994*
- the *Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994*
- the *Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994*

Levies are collected under the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, and the levy rates are prescribed in the Regulations to the Act.

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 wholesale value of certain veterinary product sales is relatively stable, while the value of agricultural product sales varies more due to seasonal and economic fluctuations. As a result, unusually low or high agvet chemical sales cause levy revenue change the following year since it is based on the previous year's sales.

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.

There are no changes to the levy rates and tiers.

Table 18: Levy rates

Based on sales	Rate prior to 30 September 2025	Rate from 1 October 2025
Levy tier 0 ** (annual product sales up to $5 000)	0.63%	0.63%
Levy tier 1 (annual product sales up to $1 000 000)	0.63%	0.63%
Levy tier 2 (annual product sales between $1 000 001 and $5 000 000)	0.35%	0.35%
Levy tier 3 (annual product sales greater than $5 000 000)	0.25%	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.

3.6.9. Cost recovery arrangements for 2025-26

Table 19 provides a complete summary of the APVMA's cost recovery arrangements for the 2025-26 CRIS.

Note: The estimated fee revenue from Items and Modules are not mutually exclusive. In most cases, the estimated fee revenue from Items and Modules may overlap as module fee revenue is often included in estimated Item fee revenue.

Estimating Item fee revenue accurately is challenging due to the high degree of year-to-year variability in the type of applications submitted. Module demand is heavily influenced by application type and has been forecast using volume data from the past 5 years and analysed statistically to identify trends.

Table 19: Registration and approvals – 2025-26 estimated revenues and costs

Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Item 1	Fee and Levy	1	116,501	116,501	415,966
Item 2	Fee and Levy	9	Modular assessment fee	343,638	964,811
Item 3	Fee and Levy	–	83,511	–	–
Item 4	Fee and Levy	–	44,664	–	–
Item 5	Fee and Levy	31	7,566	234,546	268,419
Item 6	Fee and Levy	14	6,406	89,684	154,065
Item 7	Fee and Levy	248	2,632	652,736	830,588
Item 8	Fee and Levy	96	2,632	252,672	246,665
Item 9	Fee and Levy	7	2,632	18,424	320
Item 10	Fee and Levy	160	Modular assessment fee	2,219,840	5,804,957
Item 10A	Fee and Levy	20	Modular assessment fee	57,002	19,704
Item 10B	Fee and Levy	–	Fee per legislative instrument	–	–
Item 11	Fee and Levy	1	36,205	36,205	192,337
Item 12	Fee and Levy	429	2,018	865,722	1,598,415

Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Item 13	Registration renewal fee	93	Nil fee	-	301,507
Item 13A	Fee and Levy	497	175	86 975	2,187
Item 14	Fee and Levy	200	Modular assessment fee	1,615,000	4,384,785
Item 15	Fee and Levy	1	38,766	38,776	197,429
Item 16	Fee	1	27,031	27,031	37,835
Item 17	Fee and Levy	188	5,442	1,023,096	25,286
Item 18	Fee and Levy	37	4,252	157,324	11,541
Item 19	Fee and Levy	28	350	9,800	7,914
Item 20	Fee and Levy	220	350	77,000	336,966
Item 21	Fee and Levy	104	350	36,400	2,347,727
Item 22	Registration renewal fee	56	–	–	532,152
Item 23	Fee and Levy	40	Modular assessment fee	240,800	511,891
Item 24	Fee and Levy	58	Modular assessment fee	173,080	45,287
Item 25	Fee and Levy	10	Modular assessment fee	132,630	504,651
Item 27	Fee and Levy	19	Modular assessment fee	485,419	2,364,266
Item 28	Fee and Levy	–	Modular assessment fee	–	–
Item 29	Fee and Levy	–	Modular assessment fee	–	–
8L, 8M & 8P	Fee and Levy	350	50	17,500	7,295
NV	Fee and Levy	930	50	46,500	500,606
Total registrations and approvals				9,054,301	22,615,570

Table 20: Other services – 2025-26 estimated revenues and costs

Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue	Estimated Levy/ Annual Fee Revenue ($)
GMP Licence Application	Fee and Levy	9	900	8,100	15,024
GMP Licence application and renewals Assessment fee – Category 1	Fee and Levy	33	7,500	247,500	464,213
GMP Licence application and renewals Assessment fee – Category 2,3 or 4	Fee and Levy	41	5,000	205,000	361,210
GMP Licence application and renewals Assessment fee – Category 6	Fee and Levy	57	1,800	102,600	186,453
GMP Licence application and renewals Assessment fee – Multi-category	Fee and Levy	22	7,500	165,000	288,207
GMP Licence application and renewals Low value manufacturer - Category 1 licences	Fee and Levy	1	3,750	3,750	6,956
GMP Licence application and renewals Low value manufacturer - Category 2,3 or 4 licences	Fee and Levy	2	2,500	5,000	9,274

Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue	Estimated Levy/ Annual Fee Revenue ($)
GMP Licence application and renewals Low value manufacturer - Category 6 licences	Fee and Levy	5	900	4,500	7,490
GMP Licence application and renewals Low value manufacturer – Multi-category licences	Fee and Levy	3	3,750	11,250	19,083
GMP Licence variation - GMP Audit fee	Fee and Levy	-	1,800	-	-
GMP Overseas Manufacture - Annual overseas GMP compliance assessment fee	Fee and Levy	290	1,000	290,000	537,848
HGP application or renewal fees	Fee and Levy	149	429	63,921	312,792
Certificate of Export (no technical assessment)	Fee and Levy	145	125	18,125	79,928
Certificate of Export (no technical assessment, requiring DFAT certification)	Fee and Levy	184	223	41,032	83,513
Certificate of Export (requires technical assessment)	Fee and Levy	-	375	-	-
Import Consents	Registration renewal fee		Not applicable		4,554

Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue	Estimated Levy/ Annual Fee Revenue ($)
Ag Vet Code Requests	Fee and Levy	219 hours	$95 per hour	20,805	152,115
Pre-Application Assistance	Fee and Levy	966	Tiered	169,050	1,439,889
Adverse Experience Reporting Program	Registration renewal fee		Not applicable		1,091,982
Assessment, Investigations and Monitoring	Registration renewal fee		Not applicable		3,127,927
Chemical Review	Registration renewal fee		Not applicable		1,827,630
Total other services:				1,355,633	10,016,087

3.6.10. Product registration renewal fees

The registration renewal fee must be paid by 30 May each year to maintain a product on the register for the following financial year. This fee supports the APVMA's compliance activities, processing of Item 13 applications, Consents to Import, and the costs associated with maintaining the product register. The estimated registration renewal fee revenue for renewals is shown in Table 22.

A registered product holder has the option to pay registration renewal fees 5 years in advance. From 1 October 2025 the amount payable is calculated by summing the anticipated annual fee applicable each year over the 5-year period from 2025-26.

Table 21: Registration renewal fee

	Annual fee ($)	Annual fee payable for 5 years in advance
2023-24	600	3,650
2024-25	600	3,650
2025-26	700	3,850
2026-27	750	3,950
2027-28	800	4,000

Table 22: Estimated annual product registration renewal fee revenue 2025-26

	2024–25 Budget	2025-26 Estimate
Estimated number of registered products including products with fees paid in advance	13,932	13,932
Total ($)	**8,458,000**	**10,550,616**

4. Risk assessment

The APVMA assessed its Charging Risk Assessment (CRA) for the CRIS under the Australian Government Cost Recovery Policy using the template provided by the Department of Finance. An overall CRA rating of medium risk was assessed, which was reviewed by Department of Finance.

Two implementation risks were assessed as high:

- the highest percentage increase in fee a payer may experience is greater than 10%
- significant issues were raised during the CRIS consultation

Other risks when applying the template were either low or medium resulting in an overall medium risk rating.

Other risks identified for ongoing changes to cost recovery arrangements were:

- cost recovery fees create a disincentive for new products entering the market
- the complexity of the APVMA fee structure and misunderstanding of how fees and charges are applied.

These risks are addressed by:

- continued improvements in regulatory and administrative processes and practices
- building on the best practice in ABC methodology
- collaborating closely with stakeholders and industry representatives on cost impact to business
- ensuring charging practices are transparent and defensible.

From a regulatory perspective risk management is applied to regulating agvet chemicals entering and currently in the marketplace by:

- identifying, assessing, and evaluating the risks before they can be approved for use in Australia (pre-market assessment or evaluation)
- identifying, assessing, and evaluating the risks posed by manufacturing processes before a manufacturer is issued with a licence to manufacture
- identifying, assessing, and evaluating the risks that may arise following approval of the product and licensing of the manufacturer (post-market surveillance).

5. Stakeholder engagement

At the APVMA, stakeholder engagement is a cornerstone of the cost recovery process. The APVMA believes that the success of its regulatory frameworks and financial strategies depends on the active involvement and input of our stakeholders. Engaging with stakeholders allows the APVMA to gain insights from a diverse range of perspectives, ensuring that its policies and regulatory approaches are informed by those directly impacted by its decisions. This inclusive approach not only enhances the quality of decision-making but also builds trust and credibility within the regulated community and the broader public.

Consultation on the CRIS was open for a five week period from 16 September to 18 October 2024 with publication of the CRIS consultation paper on the APVMA website. The consultation period was promoted on the APVMA's website homepage and social media channels. Advice of scheduled consultation sessions (workshops and working groups) was provided to stakeholders prior to the opening of consultation. A webinar delivered by the APVMA's CEO was published on the APVMA's website. The APVMA received significant engagement during the CRIS consultation period including:

- 52 stakeholders attended the live webinar in the first week of consultation which was delivered by the APVMA's CEO.
- Two workshops and three working groups were facilitated by an independent facilitator and attended by 39 stakeholders.
- 13 written submissions were received comprising of:
    - 8 industry associations
    - 2 chemical suppliers
    - 1 veterinary vaccines manufacturer
    - 1 non-profit organisation
    - 1 individual
- 171 unique views of the APVMA consultation hub webpage.

The consultation paper proposed three scenarios for industry to consider, each of which were aimed at ensuring the APVMA can continue to operate effectively and sustainable. The first scenario proposed to return the APVMA to the policy position for 40% recovery of fee-for-service costs through fees, aligned with the actual cost of operations and accounted for inflation since 2019. Scenario 2 included expanded operations to eliminate resource shifting and enhance regulatory performance. Scenario 3 proposed to implement operational and technological reforms funded by an increase in levy rates. All three scenarios included the proposal to move to an annual CRIS update cycle to limit the significant inflationary driven increase in costs that is occurring with the 3-5 year CRIS update cycle.

Consistent topics raised throughout the consultation process included:

- A preference for scenario 1 with a clear rejection of scenarios 2 and 3.
- Mixed views on the transition to an annual CRIS process, some stakeholders preferring more frequent updates thereby avoiding large and sudden inflationary increases, other stakeholders sought certainty in fees over a number of years.
- Concern about the level of efficiency and transparency demonstrated by the APVMA.

- Submissions from industry groups which advocated for various reforms to the regulatory system.
- Questions from industry groups on the reliance on levies including requests for the levy structure to be revised.
- The assertion that the timeframe provided for stakeholder engagement was insufficient considering the quantum of the change.
- Concern that implementation from 1 July 2025 would adversely impact entity budgets.
- Concerns that the increase in fees would act as a disincentive to the introduction of new products or registering products in Australia.
- Concerns about the impact the increase in fees would have at the farm gate.
- Questions regarding the quantum of the increase in staffing costs since 2019 and whether efficient regulatory activities were driving this increase.

The APVMA thanks stakeholders for their engagement throughout the consultation process and notes that the majority of feedback received was related to regulatory changes. The APVMA will continue to pursue efficiency improvements through investigation of regulatory system changes which includes active engagement with the Department of Agriculture, Fisheries and Forestry and other agencies as required

The change to the annual review of the CRIS is in line with the requirements of the Charging Framework which states that “the CRIS also becomes a continuous disclosure tool being updated at least annually.”

In response to stakeholder feedback the APVMA has taken action to maintain the application fees at the same rate as the 2023-25 CRIS. This provides the APVMA with the opportunity to investigate stakeholder concerns regarding operational efficiency and take action to realise efficiency gains where possible, without placing additional financial pressure on applicants. A future CRIS will be developed for implementation on 1 October 2026 which will include the outcomes of any operational efficiency analysis and realignment of costs to activities.

The feedback from the submissions was put forward to the Minister for Agriculture, Fisheries and Forestry for consideration along with the proposed fees and charged for 2025-26. The Minister approved the changes to the APVMA fees, charges and levies for 2025-26, commencing from 1 October 2025.

6. Financial performance

6.1. Financial estimates

The financial estimates in Table 23 and Table 24 outline the cost recovery position for 2025-26.

Table 23: Forecast operating results 2025-26

Budgeted income & expenditure	2024-25 Budget ($)	2025-26 Forecast ($)
Total industry income	**42,042,190**	**44,421,549**
Appropriation	2,265,000	2,265,000
Own-source revenue	304,000	304,000
Total income	**44,611,190**	**46,990,549**
Employee	34,085,711	34,085,711
Consultants/Contractors	4,189,579	4,189,579
ICT Related	7,035,811	7,035,811
Contracts & Supplies	1,112,160	1,112,160
Travel	595,000	595,000
Depreciation	2,780,195	2,780,195
Total BAU expenditure	49,798,456	49,798,456
Budget: surplus/(deficit) from ordinary operations	**(5,187,266)**	**(2,807,907)**

Table 24: Industry contribution forecast 2025-26

Industry Income	2024-25 Budget ($)	2025-26 Forecast ($)
Levies	23,145,000	23,145,000
Annual renewal fees	8,458,000	10,550,616
Product application fees	7,448,190	7,270,993
Good Manufacturing Practice	1,056,000	1,042,700
Actives, Permits and other fees		
Actives (Item 15 to 18 and 24)	1,248,000	1,419,307
Permit fees (Items 19 to 23)	364,000	364,000
PAA	165,000	169,050
HGP fees	65,000	63,921

Certificates Of Export	56,000	59,157
Agvet Code Requests	21,000	20,805
Penalties	16,000	16,000
Total industry income	**42,042,190**	**44,421,549**

Table 25: Three-year forward financial estimates 2025-26 to 2028-29

	2025–26 Forecast $'000	2026–27 Forecast $'000	2027-28 Forecast $'000	2028-29 Forecast $'000
Expenses	49,798	55,490	56,092	56,092
Revenue	46,991	55,490	56,092	56,092
Surplus/(deficit)	**(2,808)**	**0**	**0**	**0**

6.2. Financial outcomes

The Commonwealth Government Charging Framework includes performance requirements based on Section 38 'Measuring and assessing performance of Commonwealth entities' of the PGPA Act. These requirements state that:

- 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 26 shows the actual operating results from 2019-20 to 2023-24 and the 2024-25 budget forecast. The objective is to maintain a balanced position over the long term, recognising that the operating results can vary between deficits and surpluses each year.

Between 2013-14 to 2018-19 APVMA ran yearly operating deficits totalling $15 million. Following the implementation of a financial plan and new fees in 2020-21, with good economic conditions resulting in an above average levy income, the APVMA was able to reverse the impact of the $15 million accumulated deficits with running annual average surpluses of $5 million between 2020-21 and 2023-24.

This provided APVMA with the financial capacity to run an operating $5.187 million deficit in 2024-25. There is no capacity to run an operating deficit beyond 2024-25.

From 2024-25 onward the APVMA will enter a period of operating deficits unless income increases or costs are reduced.

Table 26: Actual operating results 2019–20 to 2023-24

	2019–20 Actual $'000	2020–21 Actual $'000	2021–22 Actual $'000	2022–23 Actual $'000	2023–24 Actual $'000	2024-25 Budget $'000
Expenses	41,154	36,385	36,016	42,122	48,397	49,798
Revenue	42,952	43,423	43,687	47,208	51,572	44,611
Surplus/(deficit)	**1,798**	**7,038**	**7,671**	**5,086**	**3,175**	**(5,187)**

6.3. The APVMA's financial reserve

The APVMA's revenue significantly fluctuates year-to-year due to varying sales of agvet chemicals influenced by changing environmental conditions. To manage this variability, the APVMA aims to maintain adequate cash levels for liquidity (working funds) and financial sustainability (a financial reserve), which are part of its equity. Without sufficient working funds and a financial reserve, the APVMA risks facing periods where liabilities could exceed its assets, leading to solvency and cash flow problems.

APVMA financial reserves come in 3 parts:

- Working funds based on three months of operating expenses.
- Restricted cash reserve for financial sustainability that is used to offset an operating loss in a financial year from a downturn in income receipts and current liabilities (including staff entitlements).
- Capital replacement reserve equal to accumulated depreciation.

All current liabilities at the end of June each year are funded through the restricted cash reserve.

The APVMA aims to maintain a financial unrestricted cash reserve of $14 million in equity (predominantly cash), which is approximately 3 months of operating expenses to accommodate fluctuations in revenue and expenses. This reserve includes a base limit of $5 million in working funds, covering 2 pay periods, $1.5 million in expense payments, and $0.5 million as a contingency for each month.

The accounting treatment required for managing the APVMA's revenue collection creates a timing issue in cash flows. Without an adequate reserve, the APVMA may be unable meet its liabilities during October and April each year. This situation has been ongoing since 1 July 2014, after all industry fees were required to be recorded on a cash basis.

The receipting of industry funds is governed by the invoicing timeframe provided by the Administration Act. Levies are invoiced in December each year, with an option for a 50% part payment upon invoicing and the balance due by 15 June the following year. Other fees, such as product renewal fees, are invoiced for payment in May. These funds are restricted at the end of the financial year and used to cover outgoings from July to March the following financial year.

7. Non-financial performance

The APVMA is committed to transparently reporting on non-financial performance outcomes related to our regulatory charging activities. Non-financial performance indicators are designed to reflect changes in stakeholder requirements, service demand and compliance levels, which are influenced by pricing adjustments and changes in service delivery.

7.1. Performance outcomes monitoring and reporting

The APVMA publishes performance outcomes which are available on the APVMA website and updated quarterly, with annual allowing stakeholders and the public to evaluate the effectiveness and impact of the APVMAs regulatory services. Further, the APVMA provides detailed analysis of performance in the annual report. These reports cover all the APVMAs regulatory decisions and demonstrate the responsiveness to stakeholder applications.

7.2. Continuous Improvement

The APVMA remains focussed on identifying efficiency opportunities through

- Review of regulatory processes to identify opportunities to streamline or change processes to decrease application assessment timeframes
- System modernisation to improve user experience and streamline application process
- Enhanced data analytics to provide greater insights into process efficiency and support more transparent costing
- Internal quality audits that contribute to the identification of improvement opportunities and uphold the APVMAs high quality regulatory decision making

Non-financial performance measures will be continually reviewed and assessed for their appropriateness to deliver necessary insights to support the APVMAs regulatory processes and cost recovery framework.

8. CRIS approval and change register

The CRIS approval and change register is captured in Table 27 and details the dates, basis, and approver for changes to the CRIS.

Table 27: CRIS approval and change register

Date of change	CRIS change	Approved	Basis for change
16/09/2024	CRIS consultation paper released for stakeholder consultation	APVMA Board	
22/11/2024	CRIS approval	APVMA Board	
18/12/2024	Agreement to the CRIS	Minister for Agriculture, Fisheries and Forestry	

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Appendix

Glossary

Term	Description
Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
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
APVMA Improvements Bill	*Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021*
CEO	Chief Executive Officer
Charging Framework	Australian Government Charging Framework
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.
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 three broad Items: • Fees for goods and services • Cost recovery' taxes (primarily levies, but also some excises and customs duties).
Cost Recovery Policy	Australian Government Cost Recovery Policy
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

Term	Description
CRIS	Cost Recovery Implementation Statement. A statement documenting compliance with the cost recovery policy.
DAFF	Australian Government Department of Agriculture, Fisheries & Forestry
Fee – Fixed	A predetermined fee charged for the assessment of an Item.
Fee – Modular	A fee charged for the assessment of a module.
GMP	Good Manufacturing Practice.
GMP Code	Australian code of good manufacturing practice for veterinary chemical products
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
Module	A component of an assessment that includes the level or type of assessment, as set out as Items in the table in Schedule 7 to the Agvet Code Regulations.
MQL	Manufacture Quality Licensing
PAA	Pre-application Assistance
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