Australian Government

Australian Pesticides and Veterinary Medicines Authority

Consultation Paper

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 July 2025 to 30 June 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.

Comments and enquiries regarding copyright:

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

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

Contents

List of figures

List of tables

1. Executive Summary

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has undergone significant operational change in recent years, while working to improve timeframe performance and operational efficiency. The APVMA has worked to adapt and improve its services to meet contemporary demands of the community, the industry and the Government.

Since the last comprehensive CRIS update in 2019, the APVMA has increased staff resources to ensure it is able to meet the full suite of its regulatory responsibilities. This increase in staffing resources, combined with the general increase in the cost of doing business since 2019, are the drivers of the changes to the current cost base of the APVMA and the budgeted deficit for the current financial year.

From 2019-20 to 2023-24, the APVMA managed an average operating surplus of $5 million, overcoming previous deficits. However, projections indicate potential ongoing deficits from 2024-25 onwards due to inflation and fluctuating funding, further influenced by rising wages and operational costs. This situation necessitates a considered realignment of fee structures and resource allocation to ensure financial sustainability and the APVMA recovers costs of operating.

The APVMA has proposed 3 scenarios that would reset the APVMA's cost recovery arrangements. Each scenario addresses the risks and financial implications of maintaining current fee structures:

1. Maintain operating structure: This scenario maintains current service levels and operating model. The focus will be on consolidating operations with fee structures to manage financial demands, without expanding the workforce or increasing service levels above 2023-24 performance. There would be an increase fees to recover costs based on historical costs and the 2024-25 budgeted expenditure profile.
2. Operational expansion: Scenario 2 proposes an increase in budget and resources to eliminate the need for resource shifting between activities. It would increase the current budget to include an additional $3.5 million in employee costs and $3 million in ICT-related expenditure, with fees adjusted to recover these costs. This aims to deliver activities necessary for a world-leading regulator, without changing levy rates.
3. Strategic reform: The purpose of this scenario is to extend beyond current cost recovery and fund innovation. It will focus on discussions with industry about funding, technological and operational reforms aimed at enhancing regulatory performance. While several pathways could be considered, this scenario provides a comparative option, where expenditure levels and fees remain the same as in Scenario 1, with the difference being an increase in levies to be directed to agreed project spending in response to identified reforms.

Each scenario is designed to balance the need for operational reform, address funding deficiencies, and prepare the APVMA to handle future challenges effectively. The scenarios underscore the importance of investing in continuous improvement, particularly in cybersecurity and business process optimisation, to enhance service delivery and operational efficiency.

APVMA is at a critical juncture where strategic decisions and investments are crucial to ensuring its role as a world-leading regulator of agricultural and veterinary chemicals. By moving to an annual CRIS review and implementing the proposed changes, the APVMA aims to achieve financial stability, operational efficiency, and compliance with evolving regulatory requirements, ultimately strengthening its long-term sustainability and effectiveness as a regulator.

2. 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

This Consultation Paper for the Cost Recovery Implementation Statement (CRIS) provides 3 charging framework scenarios for stakeholders to consider and provide feedback on. The paper shows:

- The current charging structure (as is for 2024-25).
- Scenario 1 - Align with current cost recovery policy for fees and levies at current budgeted activity levels.
- Scenario 2 - Enhanced resourcing levels cost recovered.
- Scenario 3 – Funding future reform programs via levy adjustments.

2.1. Purpose of the Cost Recovery Implementation Statement

The CRIS provides information on how the APVMA implements cost recovery charging for the assessment, registration and regulation of agricultural and veterinary chemicals in Australia. It reports actual financial and non-financial performance information for the regulation of the agvet chemicals industry and contains financial and demand forecasts for 2025-26. The APVMA will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

The APVMA is 95% cost recovered from registrants of agvet products. This consultation paper seeks industry feedback on revised pricing to address APVMA's projected funding shortfall from 2024-25.

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 cost recovery 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.

The wholesale value of certain veterinary product sales stays 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.

2.1.1. 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 agricultural and veterinary 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.

In July 2023 the then Minister for Agriculture, Fisheries and Forestry, Senator the Hon Murray Watt, directed the APVMA to prioritise post-market reviews of certain existing chemistries (chemical reviews) in line with policies under the National Registration Scheme for Agricultural and Veterinary Chemicals. To implement this direction, the APVMA reallocated certain internal scientific and technical resources, and noted this would impact the timelines for registration-related activities (as noted in the 2024–25 Portfolio Budget Statement). The APVMA is carefully balancing its legislative responsibilities to manage this directive effectively.

The APVMA is committed to ongoing engagement with government and stakeholders, ensuring transparency regarding timelines and enhanced regulatory activities for chemical reviews. This Consultation Paper includes the current increased regulatory activity in post-market supply and enforcement, and this is carried across all 3 scenarios.

3. Policy and statutory authority to 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.

3.1. 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 the 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.

As the APVMA is a corporate Commonwealth Entity under the *Public Governance, Performance and Accountability Act 2013 (PGPA Act)*, the Minister for Finance has made a 'government policy order'[1] that the APVMA 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 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 to be recovered via 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.

3.2. Statutory authority to charge

The APVMA, established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, 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 is a corporate Commonwealth entity under the *PGPA Act*.

3.2.1. Authority to impose regulatory charges

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

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

[1] Public Governance, Performance and Accountability (Charging for Regulatory Activities) Order 2017, https://www.legislation.gov.au/F2017L01073/latest/text, 23 August 2017

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

3.2.2. Recent legislative amendments

By 7 March 2022, most provisions from the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021* commenced, which included:

- extensions to limitation periods for registering new chemical uses
- reduced regulatory burden for variation applications
- civil penalties for providing false or misleading information
- improved transparency of voluntary recalls.

The costs associated with these legislative improvements have been accommodated within the current APVMA budget.

3.2.3. 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.

3.2.4. 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*.

3.3. Regulator Statement of Intent 2023

This APVMA Statement of Intent outlines the Board of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) response to the priorities of the Australian Government for the APVMA, as expressed in the Ministerial Statement of Expectations issued by the Senator the Hon Murray Watt, Minister for Agriculture, Fisheries and Forestry (dated 12 September 2023).

The APVMA will work to meet the expectations of the Minister, and the direction of 13 July 2023, in a manner consistent with its broader regulatory responsibilities as described in legislation, including the Agricultural and Veterinary Chemicals (Administration) Act 1992 and the Agricultural and Veterinary Chemicals Code Act 1994.

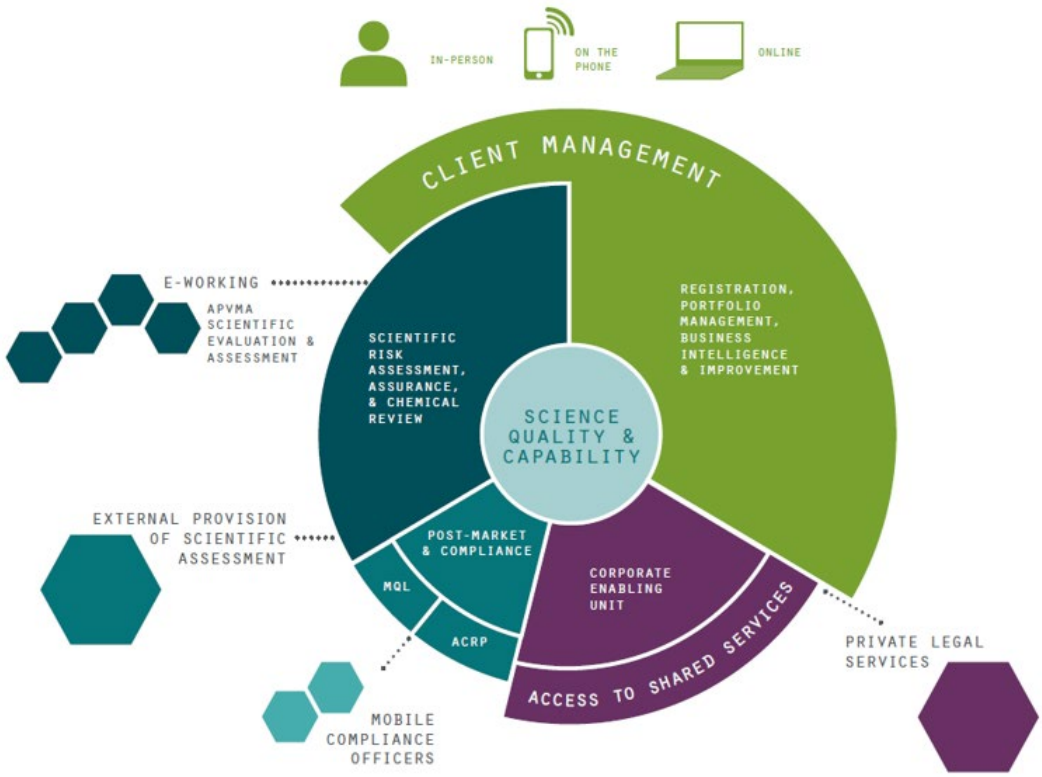
4. APVMA evolving operating environment

4.1. Ongoing operating model and Impact of disruption

The APVMA's journey over the past few years has been marked by major operational disruptions, whilst delivering significant regulatory achievements, proactive responses to emerging biosecurity threats, and substantial internal transformations. The organisation has faced numerous challenges, such as the COVID-19 pandemic, establishing a new office in Armidale and responses to various pest outbreaks, all while restoring its statutory timeframe performance and implementing crucial reforms.

The need for stability during such challenging times limited the APVMAs ability to reflect upon its operating model and make changes to the numerous often simultaneous disruptions. Now that business operations have normalised, the APVMA will undertake a considered review of its operating model to ensure continued high performance and effective delivery of regulatory activities.

Figure 1 Final business operating model



The new operating model came completely into effect in 2019-20 and coincided with improving levels of regulatory performance, chemical reviews, world first registration and ICT transformation to cloud based infrastructure. However, ongoing environmental and legislative influences since that time have limited the APVMA’s ability to validate the effectiveness of the operating model to support the high-performance delivery across all APVMA regulatory activities. Despite these challenges, statutory timeframe performance has improved significantly across the full breadth of the APVMA’s pre-market regulatory functions, including:

- pesticides
- veterinary medicines
- permits (standard and emergency).

During 2020-21, the APVMA adapted to changes caused by the COVID-19 pandemic, ensuring business continuity, supporting remote work, and creating a remote audit protocol for licensing of veterinary manufacturing facilities. This period of disruption was intensified by the need to manage requests for emergency permits for biosecurity incursions including the mouse plague, fall armyworm, khapra beetle, grasshoppers and Mediterranean and Queensland fruit fly. Despite these challenges, the APVMA improved its performance on statutory timeframe performance and implemented most of the from the 2017 ANAO performance report, including a quality management system and improved performance reporting.

Analysis of timesheet data identified that a key reason for improved performance during periods of business disruption was the large amount of unpaid overtime worked by staff between 2020-21 and 2022-23. However, this approach was unsustainable, leading to the need for increased staffing levels to ensure continued delivery of regulatory processes and to maintain performance timeframes.

The business disruption continued into 2021-22 with the implementation of major legislative reforms, following passage of the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019* (Improvements Bill) in December 2021, alongside the creation of APVMA Board. These changes, along with the ongoing COVID-19 challenges did not prevent the APVMA from responding effectively to biosecurity emergencies including, varroa mite and rabbit haemorrhagic disease (calicivirus) virus type 2 strain (RHDV2). The APVMA also completed several notable world-first registrations, and maintained strong timeframe performance, especially for permits.

In 2022-23, further significant organisational reforms took place, including changes to the APVMA Board and senior leadership, and a Ministerial Direction on Chemical Reviews. Two separate reviews into APVMA governance and culture were conducted, leading the APVMA Board and Executive to recognise the need for a major shift in governance, culture, corporate functions and operating models. Since then, the APVMA has begun establishing an in-house legal function, reform, project management, risk management, integrity and general governance functions, with improvements made to human resources, finance, and compliance functions.

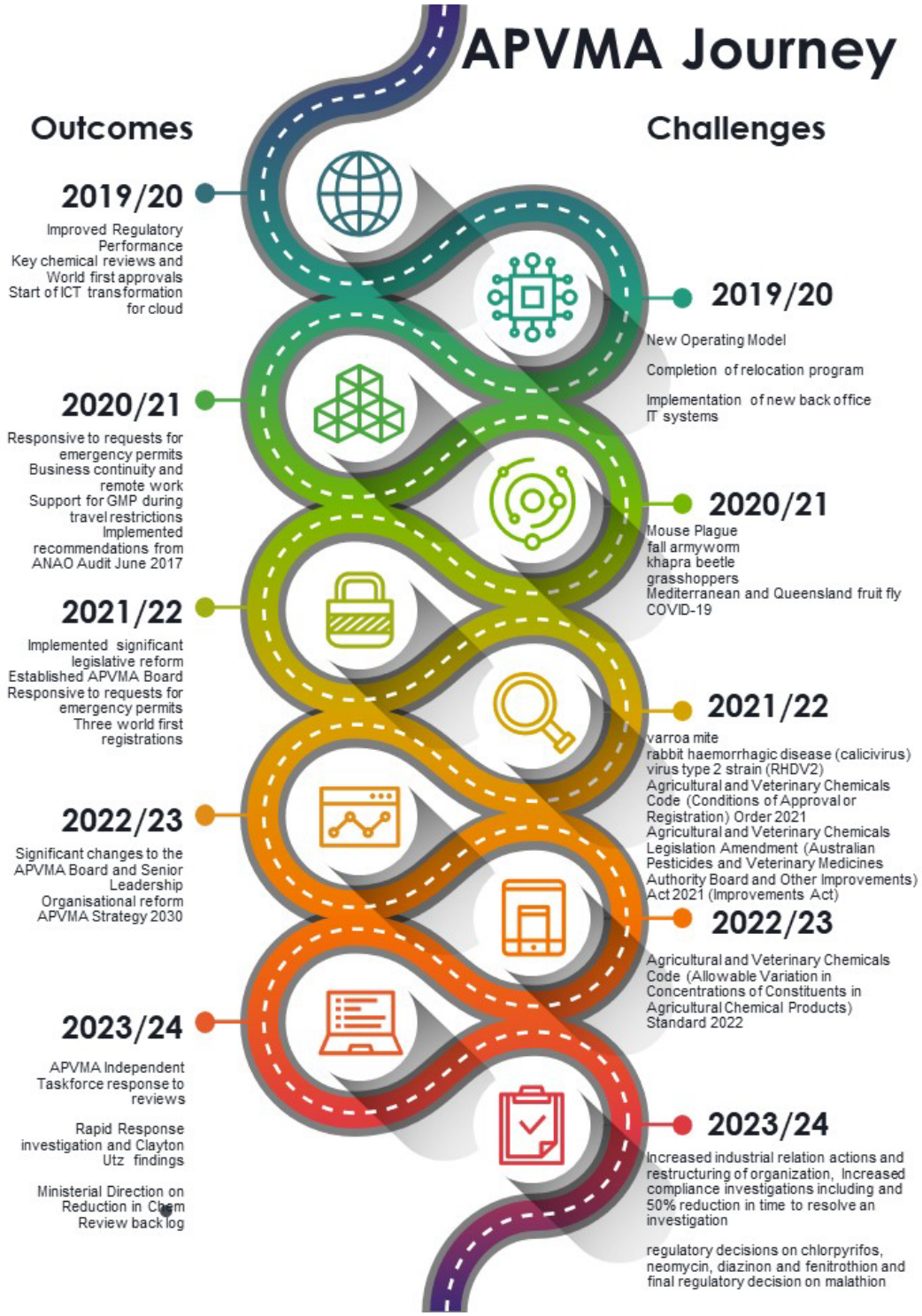
At the commencement of 2024, the APVMA board set a clear roadmap to 2030, focusing on improving regulatory outcomes, along with reallocating resources to meet the requirements of the Ministerial Direction on chemical reviews.

While the APVMA faces cost and operating pressures as part of its daily activities, the pathway to improving regulatory outcomes necessitates further new and additional costs and investments to:

- maintain its financial position and viability
- continue enhancing business systems including information systems and cyber security
- eliminate the practice of cost shifting between post and pre-market activities, ensuring all APVMA teams have the skills and capacity to meet demands
- strengthen and continue to build compliance operations capability and capacity

- re-establish critical corporate functions such as General Counsel, Governance Records, and Knowledge Management, which were significantly reduced during the implementation of the 2018 operating model
- establish a dedicated reform team to manage new and ongoing legislative changes, allowing operational staff to focus on scientific work
- introduce project management capability and improve the risk management systems and practice
- improve staff culture and people management practices, particularly from the lows of 2022, with an ongoing development and training program to be completed over the next four years.

Figure 2 APVMA journey roadmap



4.2. Operational changes and efficiency impacts

In 2019, the Rural and Regional Affairs and Transport References Committee published the findings of their inquiry into the independence of APVMA's regulatory decisions. At that time, timeframe performance for major pesticide permits was below 50%. By 2022-23, the APVMA had improved this to over 95%.

4.2.1. Permit applications and emergency response

The APVMA has successfully reduced the timeframes for all permit applications, including emergency permits, over the past 4 years. During this time, biosecurity-related emergency permits have addressed issues such as lumpy skin disease, foot and mouth disease, and various pest outbreaks, including varroa-mite. Prioritising emergency permits is vital because timely action can prevent major agricultural and economic damage, protect public health, and ensure the safety of food supplies. The APVMA's quick response has been key in reducing these risks. Additionally, the APVMA contributed important insights during 2 Senate inquiries on biosecurity incursions, emphasising its crucial role in protecting Australia against current and emerging pest and disease threats.

4.2.2. Registration management and chemical review

As a small agency with a significant regulatory remit, the APVMA balances its responsibilities within its limited resources and budget. While pre-market timeframe performance has been world leading in recent years, completing the review of several chemicals already on the market has been significantly delayed.

In early 2022, recognising the need to focus on chemical reviews, the Board agreed to add additional technical resources in Health, Residues, and Environment. This renewed focus has highlighted the need for strengthening processes and enhancing the efficiency of chemical reviews as essential to maintaining high regulatory performance standards.

Meeting or exceeding pre-market timeframe targets is integral as it ensures that industry applications are evaluated quickly, making Australia an attractive market for new chemistries. This is important for keeping Australian farmers competitive globally, as many newer chemistries are also more environmentally safe than the older ones they replace, benefiting both the agricultural sector and the broader environment.

4.2.3. Pre-application assistance (PAA)

PAA is a vital service provided by the APVMA to improve the quality of regulatory submissions. This proactive support helps streamline approvals and ensures submissions meet the regulatory standards, reducing delays and rejections.

With the increasing complexity of submissions, particularly with new chemistries and novel technologies, the demand for PAA has grown. PAAs are time-consuming and require deep technical expertise and comprehensive evaluations. Due to this complexity, only about 41% of PAAs were completed on time in 2023-24.

4.2.4. Legislative reforms and compliance

The APVMA Improvements Bill, passed in December 2021, introduced 20 measures that required significant scientific input, new policies, procedures, and substantial IT changes.

These additional compliance requirements have strained the APVMA's resources, particularly the Registration Management branch. Besides handling new applications, this branch also provides technical expertise for compliance investigations and responds to public and industry inquiries.

Strengthening the compliance framework with better training and recruitment of skilled personnel will help reduce the pressure on existing staff. Additionally, updating processes and workflows is necessary to ensure the efficient delivery of regulatory services.

4.2.5. Adapting to emerging technologies

Emerging technologies such as precision application, mRNA veterinary vaccines, and RNAi pesticides are revolutionising the agricultural and veterinary sectors. To regulate these innovations effectively, the APVMA needs significant investment to improve staff understanding and update regulatory frameworks.

These technologies are complex and require specialised knowledge. Staff need training to thoroughly understand and evaluate these advancements, along with ongoing professional development to keep up with rapid technological changes.

4.2.6. Enhancing internal capabilities

Since 2019, the APVMA has been strengthening its internal expertise by growing in-house capacity and capability, allowing it to start to build succession plans and to reduce reliance on external reviewers.

By building a strong internal team, the APVMA can respond more quickly to regulatory needs and maintain a higher consistency of standards.

4.2.7. Responding to need for reform

The APVMA has developed a consolidated action plan to address the issues identified in the Clayton Utz Review, respond to the Ministerial Direction on chemical reconsiderations, deliver on the APVMA Strategy 2030, and address other key government priorities. The action plan aims to improve workplace culture, governance, and processes to ensure the APVMA continues to undertake all its regulatory functions complying with its operating obligations and maintains 'better practice'.

4.3. Operating scenarios

Over the past 4 years, demand for chemical review, compliance, enforcement, and other post-market activities has greatly increased and these increased demands are expected to continue. The APVMA's resources and systems need to keep up with this growing demand while still delivering regulatory services, meeting performance objectives and providing quality assessments.

From 2019-20 to 2023-24, the APVMA achieved an average operating surplus of $5 million, recovering from previous deficits and restoring previously depleted reserves. However, from 2024-25 onwards, the APVMA expects ongoing operating deficits. Current revenue levels are not enough to cover rising wages (11% over the life of the enterprise agreement), ICT enhancements, contract and supplier costs, and the implementation of new business reforms while maintaining necessary staffing levels.

During budget planning for 2024-25 to 2028-29, it was noted that if income stays at 2020-21 levels, the APVMA would need to cut its workforce by at least 10% (or 20 positions) and reduce routine business system enhancements. However, this would significantly increase risk, lower service levels, and reduce the APVMA's capacity to meet its regulatory responsibilities, making it an unrealistic option.

The APVMA is planning to adopt an annual CRIS cycle. Moving to a yearly review cycle will enable the APVMA to respond to market conditions. This will mean the APVMA can take a more active role in monitoring and adjusting fees to reflect the real expenses of running the agency, and industry will have greater level of predictability on fee amendments.

For the 2025 CRIS the APVMA is consulting on 3 possible scenarios:

1. Maintain operating structure: This scenario maintains current service levels and operating model. The focus will be on consolidating operations with fee structures to manage financial demands, without expanding the workforce or increasing service levels above 2023-24 levels. There would require an increase in fees to recover costs based on historical costs and the 2024-25 budgeted expenditure profile.
2. Operational expansion: Scenario 2 proposes an increase in budget and resources to eliminate the need for resource shifting between activities within the APVMA, ensuring all regulatory functions have baseline resources to meet performance objectives. It would increase the current budget to include an additional $3.5 million in employee costs and $3 million in ICT-related expenditure, with fees adjusted to recover these additional costs. This option aims to deliver activities necessary for a world-leading regulator, without changing levy rates.
3. Strategic reform: The purpose of this scenario is to extend beyond current cost recovery and fund innovation. It will focus on discussions with industry about funding, technological and operational reforms aimed at enhancing regulatory performance. While several pathways could be considered, this scenario provides a comparative option, where expenditure levels and fees remain the same as in Scenario 1, with the difference being an increase in levies to be directed to agreed project funding in response to identified reforms.

Each scenario aims to:

- balance operational reform needs
- provide adequate funding and resources
- eliminate cost shifting
- support research and training for emerging technologies.

4.3.1. Scenario 1: Maintain operating structure

This scenario proposes keeping the 2024-25 APVMA resourcing level for 2025-26, adjusts fees and increases the annual registration renewal fee. This scenario aims to balance the budget in 2025-26, countering the anticipated $5 million operating deficit, while meeting regulatory and statutory obligations. It assumes stable application numbers and a return to historically lower leviable disposals but does not account for inflationary pressures such as increases beyond one year. While this scenario would fund current operations, it lacks the capacity for significant operational reforms, responding to legislative changes, or adapting to emerging technologies without affecting other services or performance.

Additionally, without an increase to cover rising business costs or finding new efficiencies, the APVMA would likely face a deficit by 2026-27, requiring immediate cost cuts or new funding. Adopting an annual CRIS cycle would help align income and expenditure more effectively over time to account for changing demands and fluctuating industry income.

4.3.2. Scenario 2: Operational expansion

Scenario 2 proposes increasing the APVMA's budget to enhance resourcing in staff and ICT resourcing to deliver increased capacity across the full range of APVMA activities. This scenario would adjust fees and increase the annual registration renewal fee to cost recover this increased resourcing.

This scenario also proposes boosting staffing levels to balance workloads, reduce assessment backlogs, and maintain consistent delivery across all APVMA's regulatory activities consistently.

This scenario sees continued investments in business improvement and cybersecurity upgrades which are essential for maintaining the integrity and efficiency of regulatory processes. Enhancements in cybersecurity and business operations are designed to eliminate current manual work-arounds, reducing operational risks and improving service delivery and consistency. By investing in these areas, the APVMA can enhance its capacity to deliver high-quality regulatory activities while maintaining compliance with growing legislative and related requirements. This scenario anticipates that it will take more than one year for improvements to take effect.

Overall, Scenario 2 presents a balanced approach to addressing the APVMA's financial and operational challenges, aiming for long-term sustainability and effectiveness in its regulatory responsibilities, while continuing to explore future enhancements.

4.3.3. Scenario 3: Strategic reform

In Scenario 3, the APVMA would increase fees and maintain resources similarly to Scenario 1. Additionally, it proposes raising the levy rate to fund operational and technological reforms., enabling enhancements to ongoing regulatory performance. Where efficiencies are gained adjustments to CRIS settings will be made in future CRIS setting changes.

This scenario also includes reevaluating levy tiers and rates, with this model forecast to generate an additional $5 million in levy income. These funds would be allocated to reforms prioritised by the APVMA Strategy 2030. The current tier levels and structure were put in place through a scaled reduction in rates between 2005 and 2024 without any change in thresholds. To illustrate, in 2005, levy rates were:

- 0.9% for the first $1 million of leviable disposals or part thereof
- 0.55% for any amount in excess of the first $1 million of leviable disposals up to and including $5 million
- 0.4% for any amount in excess of $5 million of leviable disposals.

The current levy tier structure, unchanged since 2005, no longer reflects current economic conditions, especially considering inflation. In 2005, the levy rates were structured across 3 tiers; by maintaining the 2005 rates and indexing them for inflation had they remained, the APVMA projects it would have received an additional $16 million to in the period 2024-25.

This scenario acknowledges past challenges where the APVMA attempted to deliver significant reforms without adequate investment, often leading to under delivery of planned projects. The proposed levy changes aim to correct this by ensuring suitable investment in necessary enabling, operational and technical reforms.

This scenario would result in a $5 million surplus in 2025-26 based on projections. This additional levy income would be allocated to regulatory activities that are anticipated to occur in the 2025-26 year. Further analysis and planning will identify specific activities to be funded by these additional resources aimed at enabling improvements to the APVMA’s performance.

5. Financial summary

5.1. The APVMA's financial reserve

The APVMA's revenue fluctuates significantly 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 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 *Agriculture and Veterinary Chemicals Administration Act (1992)*. Levies are invoiced in December each year, with an option for 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.

5.2. Forecast operating results of cost recovery arrangements

The financial estimates in Table 1 and Table 2 outline the cost recovery positions for the 3 scenarios in this consultation CRIS and the APVMA's current position.

Table 1: Forecast operating results 2025-26

Budgeted income & expenditure	Current Position 2024-25 Forecast	Scenario 1 Maintain Current Operating Model	Scenario 2 Operational expansion	Scenario 3 Maintain Current Service levels and develop strategic reforms
Total industry income	**42,026,190**	**47,227,456**	**52,634,266**	**52,963,780**
Appropriation	2,265,000	2,265,000	2,265,000	2,265,000
Payment from related entities	60,000	60,000	60,000	60,000
Own-source revenue	244,000	230,000	230,000	230,000
Penalties	16,000	16,000	16,000	16,000
Total income	**44,611,190**	**49,798,456**	**55,205,266**	**55,534,780**
Employee	34,085,711	34,085,711	37,552,964	34,085,711
Consultants/Contractors	4,189,579	4,189,579	2,836,285	4,189,579
ICT Related	7,035,811	7,035,811	10,004,780	7,035,811
Contracts & Supplies	1,112,160	1,112,160	1,068,278	1,112,160
Travel	595,000	595,000	624,780	595,000
Depreciation	2,780,195	2,780,195	3,118,179	2,780,195
Total BAU expenditure	49,798,456	49,798,456	55,205,266	49,798,456
Budget: surplus/(deficit) from ordinary operations	**(5,187,266)**	**0**	**0**	**5,736,324**

Table 2: Industry contribution forecast 2025-26

Industry Income	Current Position 2024-25 Forecast	Scenario 1 Maintain Current Operating Model	Scenario 2 Operational expansion	Scenario 3 Maintain Current Service levels and develop strategic reforms
Levies	23,145,000	23,145 000	23,145,000	28,881,324
Annual renewal fees	8,458,000	10,080,931	13,937,133	10,080,931
Product application fees	7,448,190	10,341,330	11,537,964	10,341,330
Good Manufacturing Practice	1,056,000	1,175,240	1,281,560	1,175,240
Permits, and other fees				
Actives (Item 15 to 19 and 24)	1,248,000	694,756	780,271	694,756
Permit fees (Items 19 to 23)	364,000	837,824	893,240	837,824
PAA	165,000	642,390	719,670	642,390
HGP fees	65,000	151,000	162,778	151,000
Certificates Of Export	56,000	89,370	99,300	89,370
Agvet Code Requests	21,000	69,615	77,350	69,615
Total industry income	**42,026,190**	**47,227,456**	**52,634,266**	**52,963,780**

5.3. Financial performance

The Commonwealth Government Charging Framework applies to all non-corporate Commonwealth entities and selected corporate Commonwealth entities. It includes performance requirements based on Section 38 'Measuring and assessing performance of Commonwealth entities' of the *Public Governance, Performance and Accountability Act 2013 (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 3 shows the actual operating results from 2020-21 to 2022-23 including the result for 2023-24 and budget forecast 2024-25. 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 3: 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. Cost recovery

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.

The Department of Finance oversaw the APVMA's transition to a modernised ABC over a period of 9 months and included the engagement of professional services to undertake initial scoping studies and modelling. The updated APVMA cost recovery approach is an ABC that meets the requirements of the Australian Government Charging Framework.

The new model has been endorsed by the Department of Finance and has been used to develop the scenarios outlined in this CRIS consultation when calculating the costs of activities.

6.1. 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.

6.2. 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 Code of Good Manufacturing Practice (GMP). 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 4 summarises the classification of the APVMA's regulatory charging activities as pre and post market regulatory functions, and information and governance. Further details on each of these activities are provided in Table 4.

Table 4: 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	Corporate publications
		Informing policy
		Presentations and seminars
		Website
		APVMA Governance and policy
		Parliamentary
		Senate Estimates

6.2.1. 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 5 provides a detailed description of each of the current Items and their assessment periods.

Table 5: 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	18 months

Item	Description of application	Assessment period
	(c) there are no relevant maximum residue limits; and (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	Description of application	Assessment period
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
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	Modular assessment period

Item	Description of application	Assessment period
	(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
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	Description of application	Assessment period
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 (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA	3 months
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	Description of application	Assessment period
Item 18	Application to vary relevant particulars or conditions of an approved active constituent	7 months
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	Description of application	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 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 6 outlines the registration and approval cost recovery mechanisms for Items

Table 6: 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	

Type of application	Current Item List	Cost recovery mechanism
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.

6.2.2. 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 *Code Regulation* and 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*.

6.2.3. 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[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.

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.

6.2.4. 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 *Agricultural and Veterinary Chemicals (Administration) Act 1992*, 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.

6.3. 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.

6.3.1. 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 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.

In CRIS 2013-15 introduced new fees for GMP activities which were set at full cost recovery. These 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.

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

6.3.2. 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 (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.

6.3.3. 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.

6.3.4. 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.

6.4. 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.

6.4.1. 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.

6.4.2. 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.

6.5. Costs of the regulatory charging activity

Section 6.5 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 costing 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.

6.5.1. Costing methodology

The APVMA uses an 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, which was assessed as highly reliable due to external audits. Overhead costs are distributed across these pools using headcount and expenditure as cost drivers. Figure 3 illustrates the high-level process of establishing cost pools and Figure 4 illustrates the allocation of cost pools.

Figure 3 Process to establish cost pools

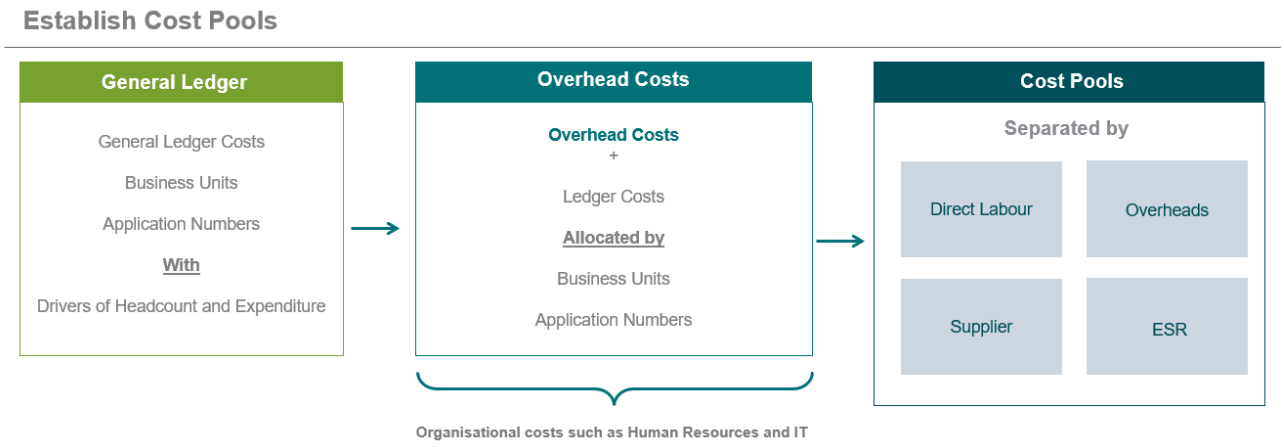
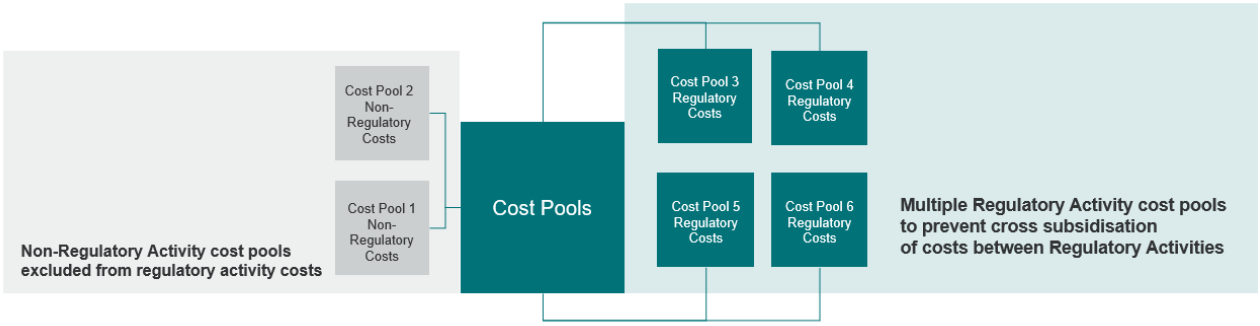


Figure 4 Overview of cost pool segregation



Cost Objects (Items)

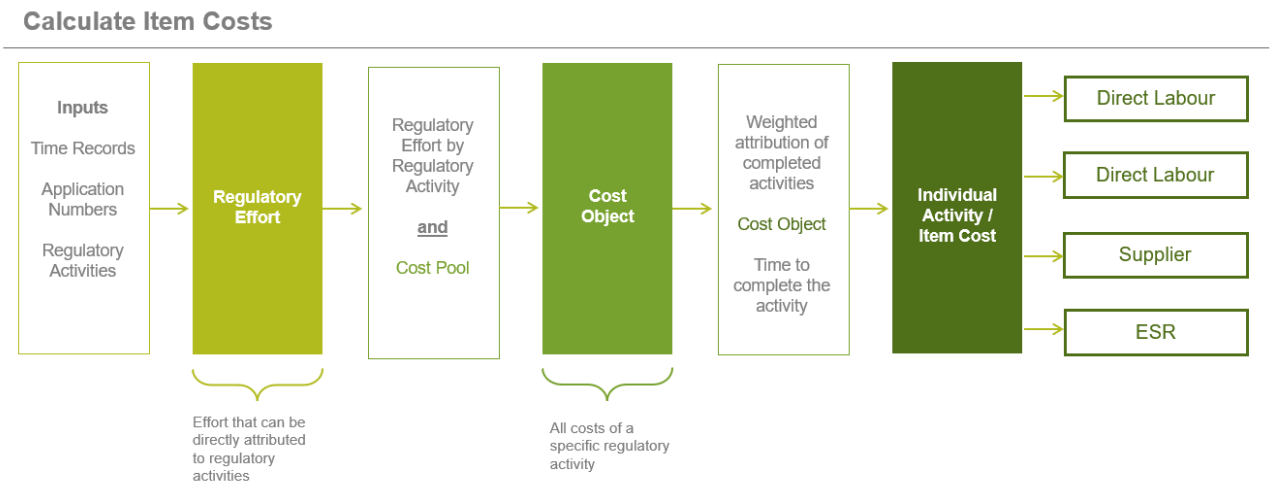
Costs are allocated to specific items and regulatory activities (cost objects) through the identification of costs and application of direct and indirect cost drivers:

- **Direct labour**: Labour costs are allocated based on employee timesheets, finance system records, and application data. Approximately 30% of APVMA labour costs were directly assigned to items.
- **Direct suppliers**: Contractors, consultants and legal costs are allocated directly to items based on application and finance system data, with 99% accuracy.
- **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 5 illustrates the process of calculating Item costs.

Figure 5: Process to calculate Item cost



Challenges with module-level costing

The APVMA's ABC model was not designed to calculate costs at the module level due to limited data. However, a carefully analysed estimate was implemented to determine module costs based on item costs, module combinations within items, and expert advice rates of effort.

Specific considerations for module costing

All model outcomes were rigorously tested for consistency, and financial outcomes are reconciled with source data to validate accuracy and prevent data loss.

6.5.2. 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 6.5.3 detail the total cost per service by direct and indirect components. The costs reported are based on the results of the ABC of the regulatory service outputs of the entity.

6.5.3. 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, with most of the costs recovered through levies. The Australian Government and the states and territory governments 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 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 2025-26 estimated total costs of registration and approvals outputs are shown in Table 7.

Table 7: Cost components of registration and approvals

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
	Service: registration and approvals			
Employee expenses	Technical and administrative assessment costs	Direct Cost	18,145,051	20,389,101
Suppliers	Outsourced activities including scientific assessment services undertaken by external entities	Direct Cost	1,486,066	1,096,870
Overheads		Indirect Cost	12,038,754	13,881,866
Total			**31,669,871**	**35,367,837**

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

The 2025-26 estimated costs for PAA activities are shown below in Table 8.

Table 8: Cost components of pre-application assistance

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
	Service: Pre-application assistance			
Employee expenses	Technical and administrative assessment costs	Direct Cost	1,066,897	1,198,843
Suppliers	Outsourced activities	Direct Cost	44,322	19,286
Overheads		Indirect Cost	497,720	573,890
Total			**1,608,939**	**1,792,019**

Consents to Import

The 2025-26 estimated costs for Consents to Import are shown in Table 9.

Table 9: Cost components of Consents to Import

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
Service: Consents to Import				
Employee expenses	Assessment and administrative services	Direct Cost	1,950	2,192
Suppliers	Outsourced activities	Direct Cost	77	31
Overheads		Indirect Cost	2,527	3,544
Total			**4,554**	**5,767**

Certificates of Export

The 2025-26 estimated costs for Certificates of Export are shown in Table 10.

Table 10: Cost components of Certificates of Export

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
Service: Certificates of Export				
Employee expenses	Assessment and administrative services	Direct Cost	171,640	192,867
Suppliers	Outsourced activities	Direct Cost	6,744	2,696
Overheads		Indirect Cost	44,214	50,893
Total			**222,598**	**246,456**

6.5.4. Monitoring ongoing compliance with regulations

Good Manufacturing Practice

The 2025-26 estimated costs of the GMP compliance assessment schemes are shown in Table 11.

The APVMA does not currently employ GMP auditors and instead relies on the services of APVMA-authorised auditors, Therapeutic Goods Administration (TGA) inspectors, and National Association of Testing Authorities (NATA) auditors to conduct audits of Licence Holders of veterinary chemical products under GMP.

TGA inspectors and NATA auditors are employed by the Commonwealth Government and a not-for-profit company, respectively while APVMA-authorised auditors are independent contractors. The APVMA-authorised auditors are independent contract who generally already provide a level of consultation services to the industry on other GMP matters.

The APVMA is considering bringing the process for the auditing function of Licence Holders for veterinary chemical products into the APVMA. This proposal aims to address several ongoing challenges including (but not limited to) the following:

- Availability of auditors with the appropriate accreditation to perform certain specialty functions (particularly category 1 immunobiological facilities).
- Actual or perceived conflicts of interest of current APVMA-authorised auditors that provide consultation services to the industry.
- Risk to Commercial-in-Confidence Information.
- Adherence with the APS Strategic Commissioning Framework[3]. As the auditing process is a core function of a regulator, APVMA proposes that audits should be conducted by appropriately trained APVMA staff.

While the business case and stakeholder engagement are yet to be completed, the APVMA suggests that this activity would be a charged on a cost recovery basis with a standard audit estimated to be a total of $21,550 or $1,315 per day for 2024-25.

This proposal has not been incorporated into the scenarios as we are yet to determine the preferred method of audit function activities. Once finalised relevant costs will be introduced into a subsequent CRIS. Costs associated with a proposed inclusion of appropriately training APVMA staff to deliver GMP Audits mentioned in section 6.3.1 above has not been included within Table 11.

[3] The APS Strategic Commissioning Framework published in October 2023 states that *"[t]he core work of the APS must be done by our core workforce – APS employees. This expectation will wind back excessive outsourcing and its impacts on the skills held and used in APS agencies."*

Table 11: Cost components of GMP compliance assessment

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
Service: GMP compliance assessment schemes				
Employee expenses	Assessment of MLS licences and imported products for GMP compliance; and management of GMP auditing	Direct Cost	1,398,587	1,728,233
Suppliers	Outsourced activities	Direct Cost	33,256	34,591
Overheads		Indirect Cost	1,506,616	1,440,446
Total			**2,938,459**	**3,203,270**

Hormonal Growth Promotant Scheme

The 2025-26 estimated costs for the HGP Scheme are shown in Table 12.

Table 12: Cost components of the HGP Scheme

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
Service: HGP Scheme				
Employee expenses	Assessment of new licences, licence renewals, licence withdrawals and HGP audits (including investigations)	Direct Cost	275,493	300,415
Suppliers	Outsourced activities	Direct Cost	23,365	24,515
Overheads		Indirect Cost	77,855	82,065
Total			**376,713**	**406,995**

Adverse Experience Reporting Program 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 13 and Chemical Review in Table 14.

Table 13: Cost components of the AERP

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
Service: AERP				
Employee expenses	Review work	Direct Cost	744,279	811,607
Suppliers	Outsourced activities	Direct Cost	63,124	66,230
Overheads		Indirect Cost	284,579	300,258
Total			**1,091,982**	**1,178,095**

Table 14: Cost components of the Chemical Review Program

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
Service: Chemical Review				
Employee expenses	Review work	Direct Cost	1,191,316	1 251 031
Suppliers	Outsourced activities	Direct Cost	-	-
Overheads		Indirect Cost	636,314	970,660
Total			**1 827 630**	**2,221,691**

6.5.5. 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 15.

Table 15: Cost components of investigation and enforcement

Expense	Inclusions	Attribution	Scenario 1 & 3 2025-26 Estimated cost ($)	Scenario 2 2025-26 Estimated cost ($)
Service: Investigation and enforcement				
Employee expenses	Non-compliance report processing, product recalls and investigations	Direct cost	1,328,851	1,449,060
Suppliers	Outsourced activities	Direct Cost	112,703	118,248
Overheads		Indirect cost	1,686,373	1,779,554
Total			**3,127,927**	**3,346,862**

6.5.6. 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 also assists in the 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 7 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.

6.6. Design of regulatory charges

Section 6.6 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.

6.6.1. Current Situation

Under the APVMA's CRIS 2020, application and permit fees were intended to fund 40% of the APVMA's assessment and registration costs. However, actual recovery has fallen short, estimated at only 24% for 2023-24. This revenue shortfall has created a significant imbalance between budgeted income and expenses from 2024-25, which is forecast to grow without remedial action, impacting the financial sustainability of the organisation. The APVMA is projecting a deficit of similar size in 2025-26 if there is no increase in revenue.

Leading up to the CRIS 2020 consultation, the APVMA recorded annual deficits of $2 and $3 million between 2014-15 to 2018-19. This over-expenditure was managed by exhausting allocated cash reserves. These allocated cash reserves were replenished following the implementation of the CRIS 2020 commencing on 1 July 2020 with a plan to restore the financial sustainability of the APVMA. The APVMA does not want to return to a position where it must consistently draw from allocated reserves. The 2024-25 budget is withdrawing funds from un-allocated cash reserves.

Relying on APVMA cash reserves to manage these shortfalls is neither financially sustainable nor responsible. Maintaining the current fee structure is not a feasible option for the ongoing financial sustainability of the APVMA, or efficient delivery of activities.

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

Addressing the deficit and economic pressure is critical for the APVMA to maintain financial sustainability and equitable cost-sharing among cost recovery payers. The Department of Finance requires ongoing reviews of fees and charges in line with the APVMA's business cycle, especially when there is volume variability or economic challenges.

The APVMA has previously reviewed its recovery performance annually and updated its pricing schedule every 2 years. Noting that during 2022, the APVMA did not increase fees as it introduced new changes to the module structure and felt it prudent to observe the impact on cost recovery arrangements before making changes to the fee structure. The APVMA intends to move to an annual CRIS cycle.

Through revising its fees and cost recovery options, the APVMA aims to achieve a robust, sustainable funding model that supports its regulatory functions, maintains activity continuity, and complies with government guidelines. This balanced approach includes the option of a fee and levy mix that will help manage financial risks and support operational outcomes.

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 heavily on levy income, which can fluctuate and create financial sustainability challenges if levy revenue declines. Additionally, while it reduces the burden compared to full cost recovery from fees, it still places a significant financial load on applicants, which could be a deterrent for those operating on tighter budgets. Balancing the need for financial stability with the goal of encouraging a steady flow of applications remains a key challenge under this model.

Full fee analysis

In 2022, stakeholders asked the APVMA to analyse the 100% recovery of costs through fees to ensure that product registration and application expenses are recovered, minimising reliance on variable income from levies.

However, this approach is not proposed as an option as it places a significant financial burden on applicants, which may lead to a reduction in the number of applications. This could result in a more consolidated market, where only larger, well-funded companies able to afford the regulatory costs, potentially reducing diversity and choice in the market, and stifling innovation.

Furthermore, full cost recovery would require a change in the fundamental operating model of the APVMA to one where its workforce is regularly resized based on new applications coming to the market as new applications would be the main source of income. This would adversely impact the ability to attract and retain specialist scientific staff and could limit how responsive APVMA could be when the number of new applications changes and potentially result in cost increases associated with applications.

The APVMA as a regulator needs to retain capacity and capability to respond in a way that is timely and effective. A move to full recovery would require significant further analysis, as the current challenges with managing year on year volatility would be amplified.

6.6.3. Revised fees

Revised registration and application fees

Table 16 provides a complete listing of the APVMA's proposed revised registration and application fees for the existing item numbers, from 1 July 2025. The table lists the fees applicable under the cost recovery proposal. 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 16: Registration and application fees from 1 July 2025

Item	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)
	Current	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
Item 1	116,501	212,987	532,467	237,729	594,322
Item 2	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 3	83,511	100,631	251,055	103,554	258,884
Item 4	44,644	53,796	134,490	55,359	138,396
Item 5	7,566	6,490	16,225	7,281	18,202
Item 6	6,406	6,964	17,411	7,793	19,483
Item 7	2,632	2,392	5,981	2,662	6,654

Item	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)
	Current	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
Item 8	2,632	2,081	5,201	2,328	5,821
Item 9	2,632	1,071	2,678	1,218	3,044
Item 10	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 10A	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 11	36,205	91,417	228,542	100,508	251,270
Item 12	2,018	2,298	5,744	2,562	6,404
Item 13[4]	Nil fee	Nil Fee	3,242	Nil fee	3,605
Item 13A[5]	175	175	179	175	197
Item 14	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 15	38,776	94,482	236,205	108,054	270,135
Item 16	27,031	25,946	64,866	28,446	71,114
Item 17	5,442	2,231	5,577	2,504	6,260

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

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

Item	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)
	Current	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
Item 18	4,252	2,598	6,495	2,886	7,215
Permit Fees are nominal, with the balance of the cost funded through levies. The nominal fee has been indexed from when it was last set.					
Item 19	350	500	633	500	719
Item 20	350	500	1,882	500	2 089
Item 21	350	500	22,924	500	25,711
Item 22	Nil fee	Nil fee	9,503	Nil fee	10,587
Item 23	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Items 24 to 29					
Item 24(a)	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 24(b)	Modular assessment fee	Modular assessment fee	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	Modular assessment fee, plus GST	Modular assessment fee, plus GST
Item 27	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 28	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
Item 29	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee	Modular assessment fee
The following fees are administrative in nature and are not part of the 40 / 60 policy. The fees continue to be set at a nominal rate.					

Item	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)
	Current	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
Section 8L	50	65	71	65	79
Section 8M	50	65	143	65	142
Section 8P	50	65	48	65	53
Notifiable Variations	50	175	588	175	660

Revised module fee

Table 17 provides a complete listing of the APVMA's proposed revised module fees from 1 July 2025, identifying the fees applicable.

Module costs were more difficult to calculate than Item costs, mostly due to limitations in the quality of data at the module level. The APVMA relied on the results and data gathered through the development of the modernised ABC model to inform the module costs. The approach included identifying significant variability in costs within similar module combinations and adjusting estimates by removing outliers and engaging with subject matter experts to validate assumptions and provide critical inputs regarding influencing factors. The resulting cost estimates were reviewed and confirmed by APVMA financial and regulatory experts, with adjustments made for insufficient data, recent operational changes and reconciliation with fixed fee Item costs to ensure reasonable and accurate module costs.

Table 17 is a proposed module 12.2 (Limits on use of information). Currently, there is a flat fee for applications where limits on use of information are required. However, there is a very wide range data with limited uses, and consequently there is greater effort and time required to record and protect this information in the system. It is therefore proposed to introduce an additional level to this module to more appropriately charge for the time required.

Module 12.1 would apply when 3 or more technical assessment modules apply, and a 12.2 would apply when fewer than 3 technical assessment modules apply, thus mirroring the finalisation modules of 11.1 and 11.2.

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

Table 17: Module fees from 1 July 2025

Module	Module, level, or type	Period for completion	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost	Fee from 1 July 2025 ($)	Estimated Cost
			Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
1 Preliminary assessment		n/a	902	1,061	2,652	1,176	2,940
2 Chemistry							
2.1	Chemistry—level 1	13 months	11,074	17,318	43,296	19,200	48,000

Module	Module, level, or type	Period for completion	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost	Fee from 1 July 2025 ($)	Estimated Cost
			Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
2.2	Chemistry—level 2	9 months	3,075	5,051	12,628	5,600	14,000
2.3	Chemistry—level 3	6 months	1,954	2,345	5,863	2,600	6,500
2.4	Chemistry—level 4	3 months	970	1,082	2,706	1,200	3,000
2.5	Chemistry—level 5	2 months	480	541	1,353	600	1,500
3 Health							
3.1	Health—level 1	13 months	36,740	60,314	150,784	66,867	167,167
3.2	Health—level 2	11 months	27,920	38,605	96,513	42,800	107,000
3.3	Health—level 3	9 months	18,980	20,205	50,512	22,400	56,000
3.4	Health—level 4	5 months	7,963	8,479	21,197	9,400	23,500
3.5	Health—level 5	4 months	4,000	4,041	10,102	4,480	11,200
3.6	Health—level 6	2 months	2,000	2,020	5,051	2,240	5,600
4. Poison schedule classification							
4.1	Poison schedule classification	13 months	2,435	2,886	7,216	3,200	8,000
5 Residues							
5.1	Residues—level 1	13 months	25,650	24,318	60,794	26,960	67,400

Module	Module, level, or type	Period for completion	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost	Fee from 1 July 2025 ($)	Estimated Cost
			Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
5.2	Residues—level 2	8 months	11,149	10,571	26,428	11,720	29,300
5.3	Residues—level 3	6 months	9,000	8,524	21,310	9,450	23,625
5.4	Residues—level 4	4 months	7,465	7,072	17,679	7,840	19,600
5.5	Residues—level 5	3 months	2,000	1,894	4,735	2,100	5,250
7 Environment							
7.1	Environment—level 1	13 months	26,390	35,972	89,929	39,880	99,700
7.2	Environment—level 2	7 months	7,659	10,463	26,158	11,600	29,000
7.3	Environment—level 3	4 months	2,979	4,059	10,147	4,500	11,250
7.4	Environment—level 4	3 months	1,490	1,719	4,298	1,906	4,765
8 Efficacy and safety							
8.1	Efficacy and safety—level 1	6 months	4,740	7,036	17,589	7,800	19,500
8.2	Efficacy and safety—level 2	4 months	1,950	2,904	7,261	3,220	8,050
8.3	Efficacy and safety—level 3	3 months	1 ,160	1,360	3,401	1,508	3,770
9 Non-food trade		6 months	1,175	1,371	3,428	1,520	3,800
11 Finalisation							

Module	Module, level, or type	Period for completion	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost	Fee from 1 July 2025 ($)	Estimated Cost
			Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
11.1	Finalisation—type 1	3 months	8,110	12,014	30,036	13,320	33,300
11.2	Finalisation—type 2	2 months	3,090	2,958	7,396	3,280	8,200
11.3	Finalisation—type 3	2 months	1,730	1,624	4,059	1,800	4,500
12 Limits on use of information							
12.1	Information Type 1		460	1,082	2,706	1,200	3,000
12.2	Information Type 2		New module	541	1,353	600	1,500

Revised other services fees

Table 18 provides a complete listing of the APVMA's proposed revised fees for other services from 1 July 2025, identifying the applicable fees.

Table 18: Other services fees from 1 July 2025

Service	Description	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)
		Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
Good Manufacturing Practice (GMP) fees						
GMP Licence application	Licence application fee	900	1,030	2,575	1,120	2,800
GMP Licence application	Assessment fee – Category 1 licences	7,500	8,630	21,575	9,405	23,515
GMP Licence application	Assessment fee – Category 2,3 or 4 licences	5,000	5,520	13,800	6,020	15,050
GMP Licence application	Assessment fee – Category 6 licences	1,800	2,030	5,075	2,210	5,525
GMP Licence application	Assessment fee – Multi-category licences	7,500	8,240	20,600	8,980	22,450
GMP Annual Licence fee	Category 1 licences	7,500	8,630	21,575	9,405	23,515
GMP Annual Licence fee	Category 2,3 or 4 licences	5,000	5,520	13,800	6,020	15,050
GMP Annual Licence fee	Category 6 licence	1,800	2,030	5,075	2,210	5,525

Service	Description	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)
		Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
GMP Annual Licence fee	Multi-category licences	7,500	8,240	20,600	8,980	22,450
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	3,750	4,315	10,790	4,700	11,750
GMP Annual Licence fee	Low value manufacturers – Categories 2,3 or 4	2,500	2,760	6,900	3,010	7,525
GMP Annual Licence fee	Low value manufacturers – Category 6	900	1,015	2,540	1,105	2,765
GMP Annual Licence fee	Low value manufacturers – Multi-category	3,750	4,120	10,300	4,490	11,225
GMP Licence variation	GMP Audit fee (if required)	1,800	2,030	5,075	2,210	5,525
GMP Overseas Manufacture	Annual overseas GMP compliance assessment fee	1,000	1,140	2,850	1,245	3,115
Hormonal Growth Promotant (HGP) fees						
HGP	Application/renewal fee	429	1,000	2,500	1,085	2,713

Service	Description	Fee prior to 30 June 2025 ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)	Fee from 1 July 2025 ($)	Estimated Cost ($)
		Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
Certificates of Export[6]						
Certificate of Export	No technical assessment	125	270	675	300	755
Certificate of Export	Requires technical assessment	230	375	780	405	860
Section 8W Agvet code requests		$95 per hour	$315 per hour	$788 per hour	$355 per hour	$888 per hour

[6] Certificate of Export fees are set at full recovery of costs.

Revised pre-application assistance fees

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

Table 19 provides a complete listing of the APVMA's proposed revised fees for PAA from 1 July 2025.

Table 19: PAA fees from 1 July 2025

Service	Description	Fee prior to 30 June 2025 ($ including GST)	Fee from 1 July 2025 ($ including GST)	Estimated Cost ($ including GST)	Fee from 1 July 2025 ($ including GST)	Estimated Cost ($ including GST
		Current Situation	Scenarios 1 & 3	Scenarios 1 & 3	Scenario 2	Scenario 2
PAA Tier 1						
Administration fee	1-unit fee	192.50	731.50	1,828.75	819.50	2,048.75
Written response, including research	2-unit fee	385.00	1,463.00	3,657.50	1,639.00	4,097.50
Meeting with applicant	2-unit fee	385.00	1,463.00	3,657.50	1,639.00	4,097.50
PAA Tier 2						
Administration fee	1-unit fee	192.50	731.50	1,828.75	819.50	2,048.75
Written response, including research	4-unit fee	770.00	2,926.00	7,315.00	3,278.00	8,195.00
Meeting with applicant	2-unit fee	385.00	1,463.00	3,657.50	1,639.00	4,097.50
PAA Tier 3						
Administration fee	1-unit fee	192.50	731.50	1,828.75	819.50	2,048.75
Written response, including analysis	6-unit fee	1,155.00	4,389.00	10,972.50	4,917.00	12,292.50
Meeting with applicant	2-unit fee	385.00	1,463.00	3,657.50	1,639.00	4,097.50

6.6.4. Pre-application assistance (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 will continue to be 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 20.

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 20.

Table 20: Pre-application assistance – rebates payable from 1 July 2025

Current Item List	Maximum rebate prior to 30 June 2025 ($)	Maximum rebate from 1 July 2025 ($)	
	Current Situation	Scenarios 1 & 3	Scenario 2
1, 2 15, 27	1,400	3,920	4,560
3, 4, 11	1,050	2,940	3,420
5, 6, 16, 17, 18	700	1,960	2,280
7, 8, 9, 10, 10A, 12, 14, 19, 20, 21, 23, 24(a) & (b)	350	980	1,140
13, 13A, 22, 25, 28, 29	**Nil**	**Nil**	**Nil**

6.6.5. 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.

6.6.6. 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.

6.6.7. 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.

6.6.8. Hormonal Growth Promotant scheme

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

6.6.9. 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 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.

Scenarios 1 and 2 proposes not change to the levy structure.

Scenario 3 includes a proposal to change the levy rates, the proposed rates associated with scenario 3 are provided in Table 21 with comparison to the current levy rates.

Table 21: Levy rates

Based on sales	Rate prior to 30 June 2025	Scenarios 1 & 2 Rate from 1 July 2025	Scenario 3 Rate from 1 July 2025
Levy tier 0 ** (annual product sales up to $5 000)	0.63%	0.63%	0.63%
Levy tier 1 (annual product sales up to $1 000 000)	0.63%	0.63%	0.63%
Levy tier 2 (annual product sales between $1 000 001 and $5 000 000)	0.35%	0.35%	0.63%
Levy tier 3 (annual product sales greater than $5 000 000)	0.25%	0.25%	0.27%

** 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.

6.6.10. Cost recovery arrangements for 2025-26

Table 22 provides a complete summary of the APVMA's cost recovery arrangements for the proposed 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 22: Registration and approvals – 2025-26 estimated revenues and costs

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Item 1	Fee and Levy	1	212,987	212,987	319,480	237,729	237,729	356,593
Item 2	Fee and Levy	9	Modular assessment fee	523,377	785,072	Modular assessment fee	585,369	878,053
Item 3	Fee and Levy	–	100,631	–	–	103,554	–	–
Item 4	Fee and Levy	–	53,796	–	–	55,359	–	–
Item 5	Fee and Levy	31	6,490	201,190	301,775	7,281	225,711	338,552
Item 6	Fee and Levy	14	6,964	97,496	146,253	7,793	109,102	163,653

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Item 7	Fee and Levy	248	2,392	593,216	890,108	2,662	660,176	990,099
Item 8	Fee and Levy	96	2,081	199,776	299,561	2,328	223,488	335,341
Item 9	Fee and Levy	7	1,071	7,497	11,247	1,218	8,526	12,781
Item 10	Fee and Levy	160	Modular assessment fee	3,209,919	4,814,878	Modular assessment fee	3,575,288	5,362,932
Item 10A	Fee and Levy	20	Modular assessment fee	30,682	46,024	Modular assessment fee	34,215	51,322
Item 10B	Fee and Levy	–	Fee per legislative instrument	–	–	Fee per legislative instrument	–	–
Item 11	Fee and Levy	1	91,417	91,417	137,125	100,508	100,508	150,762
Item 12	Fee and Levy	429	2,298	985,842	1,478,295	2,562	1,099,098	1,648,126
Item 13	Registration renewal fee	93	Nil fee	-	301,507	Nil fee	-	335,262
Item 13A	Fee and Levy	497	175	86 975	2,187	175	86,975	10,880
Item 14	Fee and Levy	200	Modular assessment fee	2 399 914	3,599,871	Modular assessment fee	2,682,996	4,024,494

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Item 15	Fee and Levy	1	94,482	94,482	141,723	108,054	108,054	162,081
Item 16	Fee	1	25,946	25,946	38,920	28,446	28,446	42,668
Item 17	Fee and Levy	162	2,589	419,418	628,964	2,906	470,707	706,130
Item 18	Fee and Levy	13	5,196	67,548	101,317	5,772	75,031	112,552
Item 19	Fee and Levy	28	500	14,000	3,714	500	14,000	6,122
Item 20	Fee and Levy	220	500	110,000	303,996	500	110,000	349,527
Item 21	Fee and Levy	104	500	52,000	2,332,127	500	52,000	2,621,958
Item 22	Registration renewal fee	56	–	–	532,152	–	–	592,845
Item 23	Fee and Levy	40	Modular assessment fee	301,076	451,614	Modular assessment fee	337,284	505,925
Item 24	Fee and Levy	58	Modular assessment fee	87,347	131,020	Modular assessment fee	98,034	147,051
Item 25	Fee and Levy	10	Modular assessment fee	254,912	382,368	Modular assessment fee	283,277	424,916

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Item 27	Fee and Levy	19	Modular assessment fee	1,139,874	1,709,811	Modular assessment fee	1,276,301	1,914,452
Item 28	Fee and Levy	–	Modular assessment fee	–	–	Modular assessment fee	–	–
Item 29	Fee and Levy	–	Modular assessment fee	–	–	Modular assessment fee	–	–
8L, 8M & 8P	Fee and Levy	350	65	22,750	2,045	65	22,750	4,172
NV	Fee and Levy	930	175	162,750	384,356	175	162,575	450,950
Total registrations and approvals				11,392,391	20,277,480		12,667,639	22,700,198

Table 23: Other services – 2025-26 estimated revenues and costs

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
GMP Licence Application	Fee and Levy	9	1,030	9,270	13,854	1,120	10,080	15,129
GMP Licence application and renewals Assessment fee – Category 1	Fee and Levy	33	8,630	284,790	426,923	9,405	310,365	465,487
GMP Licence application and renewals Assessment fee – Category 2,3 or 4	Fee and Levy	41	5,520	226,320	339,890	6,020	246,820	370,417
GMP Licence application and renewals Assessment fee – Category 6	Fee and Levy	57	2,030	115,710	173,343	2,210	125,970	189,132
GMP Licence application and renewals	Fee and Levy	22	8,240	181,280	271,927	8,980	197,560	296,489

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Assessment fee – Multi-category								
GMP Licence application and renewals Low value manufacturer - Category 1 licences	Fee and Levy	1	4,315	4,315	6,391	4,700	4,700	6,971
GMP Licence application and renewals Low value manufacturer - Category 2,3 or 4 licences	Fee and Levy	2	2,760	5,520	8,754	3,010	6,020	9,541
GMP Licence application and renewals Low value manufacturer - Category 6 licences	Fee and Levy	5	1,015	5,075	6,915	1,105	5,525	7,546

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
GMP Licence application and renewals Low value manufacturer – Multi-category licences	Fee and Levy	3	4,120	12,360	17,973	4,490	13,470	19,596
GMP Licence variation - GMP Audit fee	Fee and Levy	-	2,030	-	-	2,210	-	-
GMP Overseas Manufacture - Annual overseas GMP compliance assessment fee	Fee and Levy	290	1,140	330,600	497,248	1,245	361,050	541,403
HGP application or renewal fees	Fee and Levy	150	1,000	150,000	226,713	1,085	162,750	244,245
Certificate of Export (no technical assessment)	Fee and Levy	328	270	88,830	133,768	300	98,400	148,056

			Scenarios 1 & 3			Scenario 2		
Item recoverable service	Method of cost recovery	Forecast Demand	Fee ($)	Estimated Fee Revenue	Estimated Levy/ Annual Fee Revenue ($)	Fee ($)	Estimated Fee Revenue ($)	Estimated Levy/ Annual Fee Revenue ($)
Certificate of Export (requires technical assessment)	Fee and Levy	-	375	-	-	405	-	-
Import Consents	Registration renewal fee		Not applicable		4,554	Not applicable		5,766
Ag Vet Code Requests	Fee and Levy	219 hours	$315 per hour	68,985	103,935	$355 per hour	77,745	115,312
Pre-Application Assistance	Fee and Levy	966	Tiered	642,390	966,549	Tiered	719,670	1,072,349
Adverse Experience Reporting Program	Registration renewal fee		Not applicable		1,091,982	Not applicable		1,178,094
Assessment, Investigations and Monitoring	Registration renewal fee		Not applicable		3,127,927	Not applicable		3,346,862
Chemical Review	Registration renewal fee		Not applicable		1,827,630	Not applicable		2,221,691
Total other services:				2,125,445	9,246,276		2,340,125	10,254,086

6.6.11. Product registration renewal fees

The proposed fees and charges schedule, outlined in Table 24, is set to commence on 1 July 2025. The listed fees will apply exclusively to new applications submitted on or after this date.

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 25.

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

The calculation of the 5-year annual fee applies a methodology in line with cost recovery where the 5-year fee is calculated based on the estimated future costs it funds over the 5-year period. Modelling in the 2022-25 CRIS considered several factors including the potential increases in the renewal fee to ensure a suitable level of cost recovery over the one and 5-year period.

Table 24: Registration renewal fee

	Scenarios 1 and 3 Maintain Current Operating Model	Payable for 5 years in advance	Scenario 2 Operating Model to Match Operating Demand	Payable for 5 years in advance
2023-24	600	3,650	600	3,650
2024-25	600	3,650	600	3,650
2025-26	700	3,850	900	4,850
2026-27	750	3,950	950	4,950
2027-28	800	4,000	1,000	5,000

Table 25: Estimated annual product registration renewal fee revenue 2025-26

	2024–25 Budget	Scenarios 1 and 3 Maintain Current Operating Model	Scenario 2 Operating Model to Match Operating Demand
Estimated number of registered products including products with fees paid in advance	13,932	13,932	13,932
Total ($)	**8,458,000**	**10,080,931**	**13,937,133**

7. Risk assessment

The APVMA reviewed CRIS 2025's cost recovery risk assessment for the revenue increases for 40% cost recovery by fees using the Department of Finance's Charging Risk Assessment template. This resulted in an overall medium risk rating for the proposed APVMA cost recovery arrangements.

The template assesses high risk factors if annual revenue increases by more than 20% and the highest percentage increase a payer may experience is greater than 10%. 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
- working 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).

8. 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.

As part of the APVMA's efforts to maintain an open and collaborative dialogue with industry partners, this stakeholder engagement strategy for the 2025 CRIS will be delivered across 4 key phases:

8.1. Pre-engagement

During this phase, the APVMA will inform stakeholders that the cost recovery model and CRIS is being reviewed and provide a high-level timeline for engagement and consultation. Essential activities include convening a meeting with the CEO and representatives from the Consultative Forum and the Agvet Users Forum. The APVMA will engage with industry representative groups by formal correspondence to ensure they are informed and engaged in the process. Additionally, updates regarding the cost recovery review will be published on the CRIS the webpage to maintain transparency and accessibility of information.

8.2. Engagement

In this phase, the APVMA will actively engage with industry representative groups and regulated industries on the proposed changes to the CRIS. The consultation period will last for 4 weeks and will culminate in a summary of findings report prepared for the Minister. This consultation aims to present stakeholders with various scenarios and explanations of the cost recovery models and scenarios and seek feedback on the potential impacts across different stakeholder cohorts.

To ensure meaningful participation in the decision-making process, the APVMA will conduct a series of 3 stakeholder workshops, which will help develop mutual understanding, credibility, and legitimacy around the consultation. The APVMA aims to hold 2 working groups with regulated industries to validate and contextualise findings from other consultation activities. By reviewing information from multiple sources – submissions, workshops, meetings, and working groups – the APVMA aims to gain a comprehensive understanding of stakeholder perspectives and enhance the results from the consultation process.

8.3. Post-engagement

After the engagement phase, the APVMA will close the loop by advising stakeholders of the outcomes from the CRIS consultation process. This involves communicating the results to stakeholders, finalising the consultation report, and preparing for the implementation phase.

8.4. Implementation

In the final phase, the APVMA will implement the new CRIS, incorporating insights and recommendations gathered through extensive stakeholder consultation and by reviewing data from multiple sources. This process will involve publishing a formal notice of the CRIS implementation to stakeholders and the public, ensuring transparency and clarity.

This engagement plan seeks to ensure that stakeholders are the well-informed, actively involved, and that their feedback is thoroughly considered throughout the process, fostering a more effective and credible consultation outcome.

Page left blank-

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.
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).
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.
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.

Term	Description
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