



Australian Government
Department of Agriculture, Fisheries and Forestry

FINAL
COST RECOVERY IMPACT STATEMENT

on the

PROPOSED REVISED COST RECOVERY FRAMEWORK

for

**THE NATIONAL REGISTRATION SCHEME FOR AGRICULTURAL
AND VETERINARY CHEMICALS**

March 2005

Table of Contents

1	BACKGROUND.....	4
2	POLICY REVIEW.....	6
	2.1 The Objectives of the APVMA.....	6
	2.2 The Agricultural and Veterinary Chemical Industry.....	6
	2.3 Analysis of APVMA Activities.....	8
	2.4 Appropriateness of Cost Recovery for Key Activities.....	8
	Activity A:Monitoring ongoing compliance with regulation.....	8
	Activity B: Investigation and enforcement.....	11
	Activity C: Registration and approvals.....	12
3	DESIGN AND IMPLEMENTATION.....	18
	3.1 What are the Legal Requirements for the Imposition of Charges?.....	18
	3.2 Which Issues Should Any Legislation Address?.....	18
	3.3 How Should Charges be Structured?.....	19
	Activity A:Monitoring ongoing compliance with regulations.....	19
	Activity B: Investigation and enforcement.....	19
	Activity C:Registration and approval.....	20
	3.4 How Should Costs be Calculated and Allocated?.....	22
	3.5 Which Costs Should the Charges Include?.....	23
	Reconstitution of the APVMA’s reserves.....	26
	Application fees.....	26
	Annual Fee.....	27
	Levy.....	28
4	PROPOSED REVISED COST RECOVERY FRAMEWORK.....	32
	4.1 Proposed revised cost recovery framework.....	32
	4.2 Impact of the Proposed Cost Recovery Framework.....	34
5	IMPLEMENTATION TIMETABLE.....	35
6	REVIEW.....	37
	6.1 What Mechanisms, Including Consultation, Should be Used for Ongoing Monitoring of the Efficiency and Effectiveness of the Cost Recovery Arrangements?.....	37
	6.2 How long before the cost recovery arrangements should be reviewed again?.....	36
	6.3 Specific issues identified for review.....	36
7	CONSULTATION.....	37
	7.1 Consultation.....	37
	7.2 Summary of submissions.....	37
	Annual fee.....	38
	Application fee.....	38
	Proposed removal of the cap on the levy.....	39
	Tiered levy.....	39
	Minor use permit fee.....	40
	Research permit fees.....	40
	Reconstitution of the APVMA's reserves.....	40
	APVMA efficiency.....	41
	CRIS assumptions and analysis.....	41

Tables & Appendices

Tables:

Table 1:	Agvet Product Distribution and Sales by Company Size (FY2003-04)	6
Table 2:	Product Sales (CY2002)	7
Table 3:	Typical Activities of a Regulatory Agency	8
Table 4:	Average Annual Sales (Wholesale) over CY2001-2003 for Category 1 Applications 1997-2000	15
Table 5:	Potential of Annual Payment for any Chemical Product to Repay the Shortfall in the Cost of Assessments via the Levy	21
Table 6:	Average Annual Contribution per Product as a Percentage of the Shortfall in the Cost of Assessment of Applications (December 2003 Draft CRIS model: \$180 Minimum Levy; Flat Levy Rate of 0.74% with no thresholds or caps)	21
Table 7:	Summary of analysis of APVMA Activities and Charges	23
Table 8:	Expected Costing for APVMA Activities for FY2005/06 Distributed by Projected Fee and Levy Type	24
Table 9:	Total Contributions by Product	29
Table 10:	Average Annual Contribution per Product as a Percentage of the Shortfall in the Cost of Assessment of Applications	29
Table 11:	Comparison of Shortfall Figures for Categories 1, 12, 14, 15 & 28 with Application Fees set at Nominal rate of 40% of Cost	30
Table 12:	Comparison of Individual Contributions per Product under Cost Recovery Models	33
Table 13:	Timetable for the transition to the new levy arrangements	35

Appendices

Appendix 1:	Analysis of existing cost recovery model	42
Appendix 2:	Proposed APVMA Application Fee Categories	43
Appendix 3:	Modular Fees and Assessment Periods	46
Appendix 4:	Comparison of Current and Proposed Fee Structure for Modules and Services	49
Appendix 5:	Proposed APVMA Revenue	51
Appendix 6:	Estimated Revenue Break-up by Source	54
Appendix 7:	List of submissions	55

1 BACKGROUND

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a statutory authority within the Australian Government's Agriculture, Fisheries and Forestry portfolio. It administers the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), which is the national system for the evaluation and registration of agricultural and veterinary chemicals (agvet chemicals) and regulates them to the point of retail sale.

The National Registration Authority for Agricultural and Veterinary Chemicals, as the APVMA was previously known, was established in 1993. It operates within a national regime for chemicals management and replaces the individual State and Territory registration schemes that operated prior to its establishment.

The chemical industry and users of agvet chemicals benefit from the NRS by the provision of uniformity in the assessment and approval/registration processes and by improved access to agvet chemicals. Both of these factors have the effect of reducing the regulatory burden and associated market entry and compliance costs. The general community also benefits in terms of higher levels of certainty and consistency from a more consistent and improved risk assessment and management regime.

Under the Agreement, which established the NRS, the Australian Government and all State and Territory Governments determined that the APVMA should operate on a fully cost recovered basis, which it has been since 1996. As a consequence of the complex intergovernmental governance arrangements for the NRS, changes to the legislation and the over-arching policy framework of the NRS, including its cost recovery arrangements, should be made with the consent of all signatories to the relevant Agreement.

In addition, the legislation establishing the APVMA specifically obliges it to have regard to policies that are agreed by all Governments, as distinct to those unilateral policies of the Australian Government. Specifically, the APVMA is exempt from s28 of the CAC Act.

As a result of several reviews of the cost recovery framework, it is proposed to implement revised cost recovery arrangements for the APVMA. Developments that have led to the proposal to revise the APVMA's fee structure include:

- The National Competition Policy Review (NCP) of Agricultural and Veterinary Chemicals Legislation, completed in January 1999, made several recommendations in relation to the APVMA's cost recovery arrangements, in order to remove discrimination between firms in respect of their contribution and potential hurdles to smaller businesses seeking registration.
- An Activity Based Costing Study (ABC Study) was completed by PriceWaterhouseCoopers for the APVMA in July 1999 and has formed the basis for subsequent examinations of APVMA costs;
- The Productivity Commission conducted a public inquiry into cost recovery arrangements by Australian Government regulatory, administrative and information agencies, including the APVMA; and
- The development and implementation of a new Australian Government policy on cost recovery, adopted in December 2002, which provided further guidance on the appropriate framework for cost recovery by certain statutory authorities. In this regard, it should be noted that by virtue of a legislative exemption, these cost recovery guidelines are only regarded as best practice rather than a mandatory standard.

The NCPR recommended that:

- The levy be changed to a simple flat rate levy (applied at the point of wholesale sale) with no exemptions or caps;
- The annual renewal fee should be abolished and a minimum levy liability (per registered product) set instead; and
- Application and other registration service fees be cost reflective.

The intergovernmental response to the NCPR supported the intent of these recommendations. However, it noted that the NCPR was silent on the question of the balance between revenue sources. To address this, the Australian Government established a committee composed of representatives of Australian, State and Territory governments (the Signatories Working Group [SWG]) to examine this issue.

The SWG determined that the most appropriate and effective cost recovery model should be based on:

- A modular fee structure and the establishment of a base recovery rate of 40% for product evaluations;
- 100% cost recovery for administrative services, including export certificates;
- Abolition of the annual renewal fee; implementation of a Minimum Levy; and removal of the minimum sales levy volume;
- Removal of the levy cap; and
- The levy rate should be set as the balancing factor.

In line with the legislative arrangements for establishment of policy relating to the NRS, these principles were endorsed by the Primary Industries Standing Committee (PISC) in July 2002.

A draft Cost Recovery Impact Statement (CRIS) outlining the proposed cost recovery framework (based on these principles) was released for public comment in December 2003. The proposed changes were subsequently deferred by the Australian Government to allow for a comprehensive analysis of the wide range of important issues raised by stakeholders.

A revised draft CRIS outlining a revised cost recovery framework was released for public comment on 17 November 2004.

This final CRIS includes a report on consultation, particularly submissions received providing comments on the November 2004 revised draft CRIS.

2 POLICY REVIEW

2.1 The Objectives of the APVMA

The main objectives of the APVMA can be inferred from the legislative provisions relating to the primary function of the APVMA (i.e. the granting or refusal of an application for approval of an active constituent for a proposed or existing chemical product, registration of a chemical product, or approval of labels for containers for chemical products). The APVMA must be satisfied that the use of a chemical product (in accordance with the instructions for its use) would not be an occupational health and safety hazard and would not be harmful to people, animals or plants or the environment or trade. In addition, the APVMA must be satisfied about the efficacy of the chemical product.

The APVMA is also obliged to pursue its primary function of chemical regulation in a manner that facilitates competition within the agvet chemical and end-user industries.

2.2 The Agricultural and Veterinary Chemical Industry

The agvet chemical industry is a diverse industry comprising importers, manufacturers, packagers, wholesalers and retailers of a variety of products including veterinary medicines, companion animal products, pesticides and other agricultural products, chemicals for home garden and household use, pool and spa chemicals, timber preservatives and marine anti-fouling paints. The size of companies ranges from extremely small businesses to large multinational companies.

Primary innovators typically focus on the more financially viable niches in the market and smaller companies usually innovate in the margins of the primary innovations. The entry of this latter chemistry is extremely important in terms of extending the range of products that are available for agricultural and veterinary use.

For the financial year 2003/04, a total of 801 companies renewed registrations on a total of 7,629 agricultural and veterinary (agvet) chemical products, and the majority (748) of these companies were small companies (classified as small by the APVMA where total sales of all agvet chemicals sold by a company is less than \$5 million).

Table 1: Agvet Product Distribution and Sales by Company Size (FY2003-04)

	Small Company (Sales ¹ < \$5Mil)	Medium Company (Sales >\$5 Mil - \$20 Mil)	Large Company (Sales >\$20 Mil)	Total
Number of companies	748	32	21	801
Average total sales	\$390K	\$8.898Mil	\$63.315Mil	
Total number of products	4,157	1,327	2,145	7,629

¹ Not profit but total wholesale disposals declared to the APVMA

As Australia is a small market in global terms, sales of most products are relatively low. Approximately half the products in the market earn less than \$25,000 in sales, and more than a quarter of the registered products have no sales.

Table 2: Product Sales (CY2002)

	Product Sales Thresholds \$	No. of Products	Sales \$
Product sales of \$25,000 or less	0	2202	-
	1 - 10,000	1098	4,871,456
	10,001 - 25,000	756	12,736,919
Product sales of more than \$25,000	25,001 - 100,000	1389	77,939,864
	100,001 - 250,000	851	136,383,716
	250,001 - 1,000,000	940	474,604,941
	1,000,001 - 5,000,000	345	679,304,935
	Greater than 5,000,000	48	466,941,535
	Total	7629	1,852,783,366

The structure of the agvet chemical market has significant implications in terms of the design of any reform to the cost recovery framework. Significant action that places disproportionate financial burdens upon smaller manufacturers and low-sales chemicals has the potential to significantly reduce the range of chemical tools available - many of which are of great value in terms of agricultural production and pest/disease eradication. This aspect has been a significant consideration in the analysis of any model.

2.3 Analysis of APVMA Activities

The *Commonwealth Cost Recovery Guidelines for Regulatory Agencies* provide a useful reference point to analyse the activities of a regulatory agency and guidance on the appropriate level and mechanism of cost recovery for each type of activity conducted by regulatory agencies. Not all of these activities are performed by the APVMA, as summarised in the table below (Table 3). Where it has been identified that the APVMA performs an activity listed in the guidelines, this activity has been further analysed according to the structured questions outlined in the guidelines.

Table 3: Typical Activities of a Regulatory Agency

Activity	Relevance to APVMA
A. Monitoring ongoing compliance with regulation	Performed by the APVMA – see analysis in following section
B. Investigation and enforcement	Performed by the APVMA – see analysis in following section
C. Registration and approvals	Primary function of the APVMA – see analysis in following section
D. Issuing exclusive rights and privileges	Not performed by the APVMA. See discussion on data protection in following section
E. Information and education	Only performed by the APVMA as a part of other relevant activities
F Policy development and meeting Parliamentary requirements	Primarily performed by the Australian Government Department of Agriculture, Fisheries and Forestry out of its departmental appropriation.

2.4 Appropriateness of Cost Recovery for Key Activities

Activity A: Monitoring ongoing compliance with regulation

Q1 & 2 Is charging efficient and cost effective and consistent with policy goals?

The APVMA conducts a number of activities to monitor compliance with regulation. These include the Manufacturers' Licensing Scheme for Veterinary Chemicals, the Quality Scheme for Agricultural Active Constituents and Chemical Products, the Adverse Experience Reporting Programs and the Chemical Review Program. These are discussed separately below.

Manufacturer's Licensing Scheme

The Manufacturers Licensing Scheme for Veterinary Chemicals (MLS) ensures that veterinary chemicals are manufactured to an approved standard through a quality assurance scheme based on Good Manufacturing Practice (GMP) licences. Once an applicant manufacturer demonstrates compliance with GMP requirements, through an initial audit conducted by an APVMA-authorized GMP auditor and by taking any necessary corrective

action identified in the audit, a licence will be issued. Once a licence is issued, it will remain in force unless suspended or revoked.

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

As a condition of a licence, manufacturers are required to undergo regular audits by APVMA-authorized GMP auditors at their own expense. Full audits are conducted within a rolling audit program where the frequency of audit is determined on a number of risk factors, including the enduring compliance risk of the manufacturer.

Without the MLS for veterinary products, the costs of monitoring, investigation and enforcement, including product recalls, would be significantly higher. Charging through the licence fee would not be expected to act as a disincentive to obtaining a licence as the fees are relatively low and are paid in instalments. The costs of audits may act as a disincentive as they are borne by the licensee. However, it is likely that, even without the licensing scheme in place, most firms would still maintain quality assurance systems requiring regular audit as a matter of good business practice, including the minimisation of liabilities.

Given these considerations and the fact that it is administratively simple to identify and charge each regulated firm or individual, cost recovery principles anticipate that the costs of the Veterinary MLS should be fully recovered from the manufacturers through a fee.

Quality Scheme for Agricultural Active Constituents and Chemical Products

Many agricultural active constituents are manufactured overseas and imported into Australia. In addition, many agricultural chemical products are fully formulated overseas and imported as final products. The new Quality Scheme for Agricultural Active Constituents and Chemical Products is the mechanism by which the APVMA will ensure that all active constituents, and ultimately the products that are formulated from them, are manufactured according to the approved processes and meet the standards approved by the APVMA at the time of registration.

Under this scheme, the conditions upon the approvals of an active constituent and the registration of an agricultural chemical product will include requirements for record keeping by the registrant at their own expense as part of their product stewardship responsibilities. The applicant will be required to retain batch analysis records. This will ensure the ongoing quality of the active constituent in the final product as it places a responsibility on both the active approval holder and product registrant to ensure that each batch of the active constituent used in final product meets the approved standard. This will provide a sound basis for investigation and enforcement if needed.

In the future, the APVMA will conduct data call-ins and visits to sites to monitor compliance with the conditions of approvals and product registration.

The issue of whether licensing should occur for **agricultural** chemical manufacturers, as well as **veterinary** chemical manufacturers (see above section), was raised in the 1999 NCPR and subsequently examined at some length by an intergovernmental/industry working group established for that purpose. The working group concluded that there was no case for licensing of **agricultural** chemical manufacturers, as there is no demonstrable public risk or public health interest to require that a scheme of this kind be established.

As this quality scheme is directly relevant to the objectives of the APVMA, charging (rather than funding from appropriation) is consistent with cost recovery policy. The scheme benefits users of agricultural chemicals by ensuring agricultural active constituents and chemical products meet the approved standards and consequently are safe for use and efficacious. A levy would be an efficient and cost-effective means of recovering the costs of this scheme and the scheme is consistent with policy goals.

Adverse Experience Reporting Programs & Chemical Review Program

While registrants are compulsorily required to report any adverse experiences related to use of their registered products that they become aware of, the **Adverse Experience Reporting Programs** is an additional mechanism for voluntary reporting of adverse experiences by the general public. This is valuable feedback to the APVMA in their monitoring of the ongoing compliance of registered chemicals with the requirement that they be safe and efficacious.

Furthermore, the APVMA conducts comprehensive reconsiderations of registered agricultural and veterinary chemicals under its **Chemical Review Program**, when the APVMA has concerns about the adequacy of the basis of an existing registration and/or approval. The purpose of a reconsideration is to ensure that chemicals continue to meet the required standards for approval/registration and that they do not pose unacceptable risks to human health and safety, the environment or trade.

While specific chemicals are identified through the **Adverse Experience Reporting Programs** and the **Chemical Review Program**, any agvet chemical could potentially be the subject of APVMA actions through these programs. A fee for this activity would not be appropriate for several reasons:

- It would be difficult to accurately link costs, as the scope of reviews vary and may be dependent on the data provided;
- Adverse experience reporting and reconsiderations occur even if the registrant has adhered to all the conditions of registration. In circumstances where the registrant has acted in good faith, it would be inappropriate to charge a fee for these activities;
- In addition, the re-examination of a chemical as a result of reports of adverse experiences and/or reconsideration is likely to result in a requirement for further data and the potential for restrictions on the use of the chemical. In these circumstances, charging a fee to the registrants of products identified through these programs is likely to exacerbate any difficulties the registrants face as a result of the re-examination of the products; and
- A fee may also discourage registrants from reporting adverse experiences.

Both programs benefit users of chemicals by identifying and managing risks that were not apparent at the time of approval/registration. Both are directly relevant to the objectives of the APVMA and, therefore, in line with the cost recovery policy. As these programs potentially affect all chemical products and all end users, a levy is an efficient and cost-effective means of recovering the costs of these programs.

Activity B: Investigation and enforcement

The APVMA investigates and deals with reports that indicate that agricultural and veterinary chemicals (active constituents and chemical products) may not be compliant with the requirements of Australia's agricultural and veterinary chemicals legislation, including in terms of the constraints on claims that may be made about the efficacy of products in any associated advertising.

This function is directly relevant to the objectives of the APVMA and, therefore, in line with the cost recovery guidelines, charging (rather than government appropriation) is appropriate.

Any agvet chemical could potentially be the subject of APVMA investigation and enforcement, for example, if a fault in manufacture necessitates product recalls. If a problem is detected with one product, investigation is likely to be carried out on all similar products (even products with no sales) containing the active constituent(s) in question.

Given the activity primarily relates to their individual and collective product stewardship responsibilities, the cost should be borne by the registrants and approval holders. Indeed, they benefit collectively through assurance that competitors with unregistered chemicals are brought into compliance when they are identified. It is appropriate, therefore, to view this activity as a cost associated with the maintenance of products in the market and that approval holders and registrants should pay the cost of this program. Nevertheless, it is difficult to assign an individual cost to any particular investigation and/or compliance activity. In addition, charging fees directly to the companies under investigation or enforcement would be counter-productive as it may discourage registrants from notifying the APVMA if they become aware of faulty or dangerous products.

While most APVMA activities can be conducted primarily at its office, investigation and enforcement often require the physical presence of compliance officers at the sites under investigation. A sales based levy would not be an appropriate means of cost recovery as, while the volume of product on the market will have a bearing on the costs of investigation, enforcement and support, there are a range of other significant factors, including the nature and risk of the non-compliance and the number and geographical location of the sites under investigation.

As neither fee-for-service or a sales based levy are appropriate, the cost of the program should be evenly spread over the full suite of chemical products, with the most appropriate collection point being as a fixed amount at the time of registration renewal.

The *Commonwealth Cost Recovery Guidelines for Regulatory Agencies* discusses legal proceedings as an example of a situation where a levy could potentially undermine policy objectives. The guidelines speculate that in cases where the court awards costs, an agency such as the APVMA may be more likely to prosecute if these costs could be recovered from industry through the levy. This could also apply to a lesser extent to the recovery of the costs of court proceedings through an annual fee. However, in most instances, the APVMA, as a first option, will use its powers to obtain voluntary compliance. Prosecution is generally a last resort and cost recovery of court costs is not guaranteed.

Activity C: Registration and approvals

Question 1: Will other firms be able to ‘free ride’ on the approval of the first application?

Data Protection

In order to have an active constituent approved or a chemical product registered, the applicant must submit a package of information for assessment by the APVMA. Although these documents become the property of the APVMA, currently information provided with applications for approval of new active constituents cannot be used by the APVMA to be satisfied when considering an application for a similar active for five years². New data protection provisions commenced on 1 January 2005 when the *Australia United States Free Trade Agreement* came into force. These provisions remove an existing opportunity for free riding (by a second applicant on the approval or registration of a previous applicant). Under these provisions, data protection will apply to certain information that was required and relied upon by the APVMA in the making of the relevant registration and/or approval. In addition, only information submitted in support of applications for an approval of an active constituent, registration of a chemical product and approval of a label for a container of a chemical product or variation to a registration or label approval can receive protection.

Applicants do not apply for data protection as a separate process from approval or registration, and there is no separate legal process conferring rights or privileges. Unlike the issue of a patent, the first applicant will receive no compensation if the second applicant gains approval or registration using their own information for same or similar products.

Under the new regime, the information held by the APVMA in relation to a first application cannot be used in the consideration of another application unless the second applicant has the consent of the authorising party for the required information. The payment of compensation for the use of this information will be a private transaction, with the price to be set by the authorising party.

If a second applicant generates their own information in support of their application, this will be treated as if it is a novel application and will be assessed and charged accordingly, with no reference to the information and/or assessment and/or determinations associated with the first application.

If a second applicant pays compensation to the first applicant and receives authorisation for the APVMA to access protected data in support of the second application, there is an argument to make the application fee lower in a new category. However, the second applicant is only gaining APVMA access to the information, not to the previous decision. It is likely that additional information and assessment would still be needed, either to support different formulations or uses or to demonstrate that the product is the same or similar.

Expiry of data protection

Once the period of data protection ends for a product, the APVMA will be able to use that information in its assessment of other applications without requiring consent from the authorising party. However, the data protection periods have been set to provide an innovator with sufficient time in which to recoup the costs of generating the information through sales

² Unless consent has been given from the person who made the original application (the TRIPS Agreement – Trade Related Aspects of Intellectual Property Rights)

of products³. If this occurs, the extent of free-riding is significantly decreased and occurs only after a sufficient period of protection has been provided.

In many cases, the majority of the cost of information has been recovered in other markets and the main cost to be recouped is for information that is specific to Australian circumstances as Australia requires only a minor amount of additional data beyond that which is produced for the major markets. Consequently, the full marginal costs of entering the Australian market are significantly less than that for the primary markets.

However, given the small size of the Australian market, some products will have limited sales and some innovators may not be able to capture even these costs within the data protection period. Consequently, it is possible that some free-riding occurs once the period to recover the innovation costs has expired.

Products registered before the introduction of data protection

Some free-riding will continue as the data protection provisions are not retrospective and will not apply to information provided in support of applications submitted before 1 January 2005. This is unavoidable and is a function of the history of the relevant legislation, which established the market entry conditions that were accepted by the applicants at the time of their application.

While assessment of subsequent applications will continue to be based on information submitted for the first application, and fees will be lower, once again, it is likely that additional information and assessment would still be needed for most subsequent applications, either to support different formulations or uses or to demonstrate that the product is the same or similar. Although the original information will not be protected, this additional information would be eligible for data protection.

Questions 2, 3, 4 and 5: Is charging or a levy efficient and cost effective and consistent with policy goals?

A fee would be efficient and cost effective as:

- it is possible to establish a fee that accurately links the costs of the activities to the regulated firms or individuals; and
- the fee is administratively simple to collect as it is possible to identify and charge each regulated firm or individual.

The *Commonwealth Cost Recovery Guidelines for Regulatory Agencies* recommend that it may be appropriate to consider whether a fee is needed to discourage frivolous or vexatious demand. The APVMA's initial screening of applications discourages applications that are frivolous or vexatious in terms of the adequacy of their supporting data. However, the

³ Australia is a small market – somewhat less than 2% of the world's chemicals market, with nearly all of it imported as fully formulated products or prepared active constituents. Consequently, there is only a small manufacturing industry.

The US and the EU are the primary agvet chemical markets. Chemical innovators specifically target these markets because of their size. They factor the terms of the US and EU protection regimes into their business strategies to offset the costs of the development of a new chemical entity, other market entry outlays and a premium. It is through these mechanisms that they will recover almost all of these costs. In general, markets such as Australia are marginal and opportunistic in most cases and are not factored into the principal business decisions.

Typically, transfer of new innovation into Australia occurs significantly later than that in the primary markets. Consequently, most of the costs of innovation would have been recovered in the primary markets by the time the product enters the Australian market.

possibility remains for applications to be lodged that are frivolous or vexatious and the APVMA is required to conduct a full assessment of every proper application. If a fee were not in place, and instead the cost of evaluations was fully recovered through an appropriation, a company might be more likely to lodge a speculative application (for which the company is not paying) and there may be more such frivolous or vexatious applications. For this reason, a fee is needed for applications for registrations and approvals.

However, as discussed in the following section, there needs to be a balance between discouraging speculative applications and not discouraging potentially beneficial applications. If a fee inappropriately discourages applications that increase the range of products and/or the breadth of participants within the market, this would be contrary to the objectives of the scheme.

The effect of the registration fee on innovation

While analysis of registrations and approvals suggests that a fee is the appropriate means of cost recovery for this activity, historically the costs of registrations and approvals have been recovered through a combination of application fees and the levy, with the majority of the costs recovered through the levy. While the existing cost recovery arrangements incorporate a variable level of cost recovery through the fee for different application categories, the APVMA's activity based analysis demonstrated that existing cost recovery levels for applications averaged at around 30% recovery of the costs of evaluation.

Given the current low level of cost recovery through application fees, a transition to an cost recovery model based on 100% cost recovery through application fees would increase application fees significantly and could have the potential to result in significant industry adjustment.

The SWG determined that fees would be appropriate for registrations and approvals. However, it recommended that a nominal fee of 40% of the cost of assessing applications for approvals and registration be paid as an application fee, with the remainder recovered across the life of the product via the levy collected by companies at the point of wholesale sale and presumably transferred to the users of agvet chemicals through the pricing mechanism. The SWG considered that a higher level of cost recovery via the application fee would be a significant disincentive for new products and other innovation into the market, particularly in the case of small businesses and low volume chemical products.

A number of submissions opposed the use of the levy as the balancing factor, arguing that this constitutes inappropriate cross-subsidisation. Other submissions proposed recovery rates varying from 0% to 100% of the cost of assessing the application.

Given the variance in views on this issue, historical data on product registrations and subsequent product sales has been analysed to determine the level of sensitivity of the agvet chemical market to increases in application fees.

Fee sensitivity within the market

A major determinant of the level of sensitivity of the agvet chemical market to increases in application fees is the ability of the registrant or approval holder to subsequently recover the cost of registration through sales of the product.

Table 4 provides an indication of the average sales of new products with previously unapproved active constituents that have gained registration with the APVMA since 1997.

Table 4⁴: Average Annual Sales (Wholesale) over CY2001-2003 for Category 1 Applications 1997-2000⁵

Average Annual Sales (\$/product)	Total No. of Category 1 Applications	Product Type
0	3	Agricultural (3)
1 - 5,000	-	-
5,001 - 10,000	-	-
10,001 - 25,000	1	Agricultural (1)
100,001 - 250,000	4	Agricultural (3), Veterinary (1)
250,001 – 1,000,000	13	Agricultural (12), Veterinary (1)
1,000,001 – 5,000,000	10	Agricultural (9), Veterinary (1)
5,000,001 – 10,000,000	2	Veterinary
10,000,001 – 20,000,000	1	Agricultural
Greater than 20,000,000	-	
Total	36	Agricultural (30), Veterinary (6)

Statistics on the profit margins on agvet chemicals are not available. However, even assuming reasonable profit margins, it is apparent from Table 4 that a significant proportion of agvet chemicals registered since 1997 would provide low annual returns to many registrants.

⁴ Table 4 does not include all new veterinary products registered since 1997, as Category 3, 5 and 7 products were not analysed. Category 3 comprises products for use on a dog, cat or horse, and for which one or more active constituents have not been approved.

In addition to the 3 products that had nil sales for the 3 years from 2001 to 2003, there were 9 of the 33 other products that had nil sales in either 2001 or 2002 or both years. These may have included products that were relatively newly registered and either not yet on the market or still establishing a market.

The sales figures provided in the above table are for either wholesale sales of the product or the notional wholesale value of the product at the time of the disposal. They provide an indication of the revenue from sales of the product, but not of the profit on the product.

If average sales are also examined for other registration categories that involve innovation in relation to previously approved or registered chemicals (eg Categories 12,14,15 and 28), a significant proportion of these products are also low sales products. A registrant considering further innovation such as extending the uses of an existing product may also be deterred by a significant increase in the application fee for this. Hence, the current level of innovation in relation to existing products may also be reduced under full cost recovery through application fees and it would also be appropriate for levy-payers, as beneficiaries of innovation, to also contribute towards the cost of these evaluations.

⁵ Excluding products whose registration has been discontinued.

When considered in light of the information in Tables 1 and 2, which demonstrate the structure of the market participants, it is evident that unreasonable disincentives to approval/registration may have significant impacts on users of chemicals where low-sales products are important for limited but specific uses. These products could include:

- Products targeting rare or uncommon pests, diseases or conditions, particularly veterinary products;
- Products that are selective in their action rather than broad-spectrum;
- Alternatives to successful existing products, which require time to “prove” themselves;
- Alternatives to products whose use has been restricted eg after review or to products which are being phased out under international agreements. The amount of the application fee may determine the number of alternative products for which registration is sought.

The primary beneficiaries of a market that includes such low sales products with low rates of economic return to potential registrants/approval holders are the users of agvet chemicals, because they have more chemical tools to use and greater capacity to select a chemical product to suit their particular circumstances.

Accordingly, it is appropriate to use a levy in combination with a nominal fee, recognising that this will benefit users by reducing the regulatory and financial burden upon registration of new chemistry and extension of existing chemistry.

Category 38 applications

The APVMA estimates that approximately 82% of the increase in application numbers between 1998/99 and 2002/03 has been from Category 38 applications relating to label changes that have not attracted a fee under the existing cost recovery framework.

However, given that this activity is not capable of being predetermined in terms of who is to be affected and that the changes are primarily driven by changes to technical standards by government authorities or international bodies as a function of the health and safety standards required for continuing in the market, the cost of this activity is best treated as a fee to be evenly distributed over all registrants at the time of renewal of registration (similar to that of the investigations and enforcement function).

Conclusion: Is cost recovery appropriate for registration and approvals?

As funding of registration and approvals from an appropriation is likely to encourage frivolous or vexatious applications, cost recovery, via an application fee, is appropriate for registrations and approvals. However, cost recovery on the basis of a nominal fee in combination with a levy is the most appropriate combination to avoid structural aspects within the cost recovery framework that would discourage potentially beneficial applications, particularly those from small business and in the margins of the more profitable niches. The issue of the balance between fees and the levy is examined further in later parts of the CRIS (refer Section 3).

Permits

Is cost recovery appropriate for permits?

Minor Use Permits⁶

Minor use permits allow the use of an agvet chemical in a manner that is not on the product label and which would otherwise be illegal. Minor use permits are usually issued for the use of an agvet chemical in small, emerging or niche industries. These are often horticultural industries but also for relatively uncommon animal industries, such as alpacas. As the registrant of the chemical has made a commercial decision that registration of these uses is not commercially justified, the applicant is usually a grower or a grower organisation that require the chemicals for very specific uses. Where the permit applicant is a grower organisation, the APVMA will issue a general permit that allows the particular use without restrictions on who can use the agvet chemical in this way. In these cases, other users of chemicals who use them in accordance with the permit, free-ride on the approval of the first permit applicant (and any fees paid and any information that is required by the APVMA and relied upon in the relevant determination).

The new data protection provisions are structured to encourage industry preference away from minor use permits to approvals and registration by providing longer periods of data protection for applications that include minor uses in the initial application. In addition, information provided to the APVMA in support of a minor use permit will not receive data protection.

As growers and grower organisations (as permit approval holders) would pay both the costs of generating data and the permit fee, but cannot recoup these costs through product sales in the same way that registrants could, it is considered appropriate that a nominal fee be charged for administrative costs of processing the minor use permits with the remainder of costs (of evaluation) being recovered via a levy applied at the point of wholesale sale.

Research permits

Research permits allow use of agvet chemicals in technical trials and to generate information in support of a potential application for registration or a permit. As these permits are for specific uses with private benefit, there is no opportunity for free-riding from the permit.

As the information generated through research conducted under this type of permit can later be used to obtain registration (where upon the registrant may recoup application fees via product sales), it is considered appropriate that the applicant is charged for the cost of assessment. However, if and when a formal application for registration is lodged, the applicant would not be charged for the same assessment twice.

In terms of fee, the same arguments as for applications and registrations are relevant and it is appropriate to charge a nominal fee (at 40% cost recovery) in combination with a levy as the most appropriate combination to avoid structural aspects within the cost recovery framework.

⁶ In the December 2003 CRIS, it was proposed to remove the current fee exemption for a minor use permit from persons primarily engaged in primary production. Approximately half the submissions received were in relation to this proposal. The submissions strongly opposed the removal of the exemption and argued that this exemption addresses market failure by enabling small, niche agricultural industries, particularly in horticulture, to gain permits for uses (Minor Uses) of chemicals that are not registered uses and which are not likely to be registered by the manufacturer because the return from additional sales would not justify the cost of registration.

3 DESIGN AND IMPLEMENTATION

3.1 What are the Legal Requirements for the Imposition of Charges?

There is already a legal framework in place for cost recovery for the APVMA.

Application and other fees are provided for in the *Agricultural and Veterinary Chemicals Code Regulations 1995* made under the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*. These fees are being revised as set out in the body of the CRIS.

Levies are authorised by the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995* together with three levy imposition Acts – the *Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994*; the *Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994*; and the *Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994*. The rate and other details of other existing levies are being amended as set out in the body of the CRIS.

The *Agricultural and Veterinary Chemicals (Administration) Regulations* made under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* currently provide for fees for export certificates. It is proposed to increase the level of fees for export certificates in the *Administration Regulations*.

3.2 Which Issues Should Any Legislation Address?

The *Commonwealth Cost Recovery Guidelines for Regulatory Agencies* advise agencies to consider the level of specific guidance to be included in legislation or any regulations attached to legislation. Matters to be considered include:

- Whether legislation specifies the detail (level, rates, etc) of the cost recovery charges or provides guidance on the desirable characteristics of the charges;
- Balancing the level of certainty with the need for flexibility; and
- If detailed guidance is to be included in the legislation, whether this is consistent with constitutional requirements.

In most instances, the legislation already provides detailed guidance on the cost recovery charges, and the proposed changes amend specific details such as the amounts charged for fees, or relevant dates, without altering the intent or context of the legislation. Exceptions to this are discussed further in the body of the CRIS. The key exceptions include:

- Revised list of application fee categories;
- Modular fee structure;
- Changes to levy structure; and
- Introduction of a penalty for understating the leviable value of disposals.

These proposed changes will specify the detail of the cost recovery charges and will continue to provide a high level of certainty.

3.3 How Should Charges be Structured?

Activity A: Monitoring ongoing compliance with regulations

Who should pay cost recovery charges?

All registrants should pay for those activities associated with monitoring of compliance, as the activities are relevant to registrant's responsibility for product stewardship.

In addition, as identified in discussing the appropriateness of cost recovery (refer Section 2.4), these activities are also of benefit to users of agricultural and veterinary chemicals. With the exception of the Manufacturer's Licensing Scheme, charging companies directly for monitoring and compliance activities is neither efficient nor effective.

How should charges be structured?

Given the analysis above, and with the exception of the Manufacturers' Licensing Scheme, it was concluded that a levy is the most appropriate method of cost recovery for the individual programs included in this activity.

As a general principle, the level of regulatory effort for these programs increases in proportion with product sales.

- In the case of the Quality Scheme for Agricultural Active Constituents and Chemical Products, there will be a direct relationship between the volume of product and regulatory effort.
- In regard to the Adverse Experiences Reporting Programs (AERP) and Chemical Review, it is less clear-cut.
- As a general rule for AERP, and **all else being equal between products**, it would be more likely for a higher sales products to have a higher level of adverse reports because a higher level of use would increase the potential for an adverse experience to occur.
- While a higher level of use may not make it more likely that a product will become subject to a chemical review, it is more likely that the scope of review, data requirements and level of assessment would be increased for a high sales product.

Given that there is a proportional relationship between sales and regulatory effort, a levy based on sales is considered to be the most efficient and cost effective cost recovery mechanism.

Activity B: Investigation and enforcement

Who should pay cost recovery charges?

As discussed in the Section 2, it is the responsibility of the relevant company to sell a product that is registered or approved and that complies with the conditions of registration or approval.

How should charges be structured?

It was previously determined (when considering the appropriateness of cost recovery) that it is appropriate to view this activity as a cost of the product remaining in the market and to recover the costs of this activity as a fee at the time of registration renewal.

Activity C: Registration and approval

Who should pay cost recovery charges?

As discussed previously, the agvet chemical industry benefits significantly from this activity through a consistent system of product registration, so should contribute towards the costs of the activity. However, end-users also benefit from greater access to a broader range of chemicals, so they should also.

How should charges be structured?

After examining the appropriateness of cost recovery for registration and approval in the previous section, it was concluded that a fee is necessary, but that full cost recovery through a fee could discourage competition within the scheme. It was considered that a levy is appropriate to recover the balance of the costs. However, the issue of the split between a nominal fee and the levy needed to be examined further.

Several existing categories of applications have been examined to gain an understanding of the ability of different cost recovery models to recover the outstanding cost of registration through subsequent levies paid on the individual product.

Registrants must provide data on the disposals of their products to the APVMA in order for the levy to be calculated. These records have been analysed for applications in several different application categories (Category 1, 12, 14, 15 & 28) that were finalised during 1997 to 2000 (and maintained registration from calendar years 2001 through calendar years 2003). The levy and fees data for the calendar years 2001 to 2003 have been calculated for several cost recovery models to gain an estimate of the total annual contribution that would be made in relation to these products under the different models. These total payments have then been compared with the shortfall in the costs of assessing applications under different levels of cost recovery through the application fee.

This data does not include every application under these categories for this time period, as some may no longer be registered or be registered under a different registration number following a subsequent second application. However, extrapolating this data gives some understanding of the effect of different levels of cost recovery through application fees, and provides a comparison of the likely level of recovery of the outstanding cost of registration from products in a range of sales categories.

In assessing the ability of products registered in these categories to repay the shortfall in the cost of assessment by eventually delivering the full cost of their registration and approval over their life in the market, it is difficult to predict how long any individual product will remain in the market. However, potential ability to repay is likely to follow the general trend in Table 5:

Table 5: Potential of Annual Payment for any Chemical Product to Repay the Shortfall in the Cost of Assessments via the Levy

Average annual payments as % of shortfall	Ability to repay shortfall
0%	Never able to pay shortfall
1% - <10%	Never able to pay shortfall
10% - <20%	Probably will not repay shortfall
20% - <40%	Will repay shortfall over life of product
40% - <60%	Probably overpay over life of product
60% - <100%	Significantly overpay over life of product
100 - <200%	Significantly overpay over life of product
Greater than 200%	Significantly overpay over life of product

Using the conditions proposed in the December 2003 draft CRIS (based on a flat levy rate and 40% cost recovery through application fees) as an example of a cost recovery model based on a flat levy rate, it can be seen in Table 6 (based on the application data sampled) that, under this model most of the products examined would not repay the shortfall and that increasing the level of cost recovery through application fees does not address this. Even if the level of cost recovery through the application fees is raised to 60%, more than half the products examined would never repay the shortfall.

However, this model would have resulted in several products significantly overpaying the shortfall, and the number of products significantly overpaying would increase with an increase in the level of contribution through fees.

Table 6: Average Annual Contribution per Product as a Percentage of the Shortfall in the Cost of Assessment of Applications (December 2003 Draft CRIS model: \$180 Minimum Levy; Flat Levy Rate of 0.74% with no thresholds or caps)

Average Annual Contribution as % of Shortfall	Level of Cost Recovery through Fee							
	20%	30%	40%	50%	60%	70%	80%	90%
0%	29	27	8	8	4	3	-	-
1% - <10%	61	60	74	68	66	58	53	40
10% - <20%	11	11	12	15	20	21	16	16
20% - <40%	13	15	18	20	14	12	21	15
40% - <60%	6	5	5	3	8	13	4	12
60% - <100%	5	6	5	6	6	7	17	8
100% - <200%	2	3	4	6	6	8	7	20
200% or greater	-	-	1	1	3	5	9	16

The application data demonstrates that, in any cost recovery model incorporating a flat percentage rate levy, it would be impossible to reduce the number of products that would not repay the shortfall without increasing the number of products that overpay the shortfall.

While it has been determined that the levy should fund the balance of the cost of an application to prevent a barrier being created to registration, a flat rate will mean that levy contributions from high-sales products will contribute disproportionately towards the entry of products into the market, regardless of their risk profile or the rapidity of the shortfall being paid.

In order to introduce a level of cross-subsidisation that is more equitable, a tiered levy system is necessary. This is discussed further in the following sections on how costs should be allocated.

3.4 How Should Costs be Calculated and Allocated?

The Activity Based Costing (ABC) model developed in the ABC Study, identifies activities undertaken in the APVMA's service delivery sections and provides cost information about these sections: registration, compliance, chemical review and specific other services. Although corporate activity costs are not separately identified (as specific service delivery sections) in the model, corporate costs have been attributed in the model to provide a full cost of service delivery activities and APVMA services.

In the ABC model, cost drivers have been identified to trace resource costs to activities and the resultant activity costs to services. The principal driver used in the ABC model is the percentage of staff time taken (by band level) to perform each activity. This resource driver is used to attribute staff costs by band level to activities. With regard to corporate costs, Corporate Services Costs (Finance & Administration, Human Resources, Information Technology and Information Services) are attributed to each service delivery section using Average Staffing Level (ASL) in each of the sections. Executive type costs (CEO, Board, Executive Management, Legal, Communication and Secretariat) are attributed to service delivery sections based on survey results of time spent servicing each section (refer Table 8).

Fixed costs that do not vary with output such as rent, cleaning, light and power and depreciation on leasehold improvements are attributed on the basis of space occupied by each section. Other indirect costs associated with an activity are attributed on ASL within each section.

In completing the ABC exercise, the APVMA ensured that only the minimum costs necessary to deliver the service were included. In particular, the APVMA asset base and capital program reflect only the most cost effective utilisation of capital. The APVMA owns no real property or other significant assets.

3.5 Which Costs Should the Charges Include?

Table 7 outlines the preferred levy and fee arrangement for each activity if analysed in line with Sections 2 and 3. It should be noted that this levy and fee structure is modified by the analysis in Section 3, which deals with the rationale behind the 40% cost recovery through application fees.

Table 7: Summary of analysis of APVMA Activities and Charges

Activity	Fee	Levy	Comment
A. Monitoring Ongoing Compliance with Regulation			
Manufacturer's Licensing Scheme	Annual Licence Fee		Not reviewed ⁷ .
Quality Scheme for Agricultural Active Constituents		Flat % rate levy	Amount of regulatory effort is related to volume of product manufactured and sold in the Australian market.
Adverse Experience Reporting Programs		Flat % rate levy	
Chemical Review Program		Flat % rate levy	Timing, extent and scope of review can reflect volume of product
B. Investigation and Enforcement			
Investigation and Enforcement	Fee		To be collected at the time of registration renewal
C. Registration and Approvals			
Registration and Approvals	Nominal Fee (applied at rate of 40% cost recovery)	Tiered levy based on disposals	Remainder of costs to be recovered from users of agvet chemicals via a levy as the balancing factor.
Permits (Minor Use)	Nominal fee for administrative costs	Tiered levy based on disposals	Cost of assessments recovered from end users through levy -
Permits (Research)	Nominal Fee (applied at rate of 40% cost recovery)	Tiered levy based on disposals	Remainder of costs to be recovered from users of agvet chemicals via a levy as the balancing factor.

⁷ The fees charged for the veterinary MLS are not changed because the way the legislation presently operates the manufacturing licence scheme, any changes could constitute an acquisition of property which may offend against s.51 (xxxii) of the Constitution unless compensation was paid to existing licence holders.

The expected costing for APVMA activities for FY2005/06 have been allocated in the following table (Table 8) according to this framework.

Table 8 Expected Costing for APVMA Activities for FY2005/06 Distributed by Projected Fee and Levy Type

APVMA Activity	Expenditure	Fee Charged	Nominal Fee	Levy	Other Revenue	Total
Registration and Approval						
Pesticides Program	2,859,935					
Veterinary Medicines Program	2,852,739					
Chemistry and Residues Evaluation	2,411,103					
Advice from agencies	3,580,488					
Total	\$ 11,704,265	\$ 5,211,860	\$ 1,338,791	\$ 5,153,614		\$ 11,704,265
Compliance						
Investigation, enforcement and support	1,585,457		1,579,157	⁸ 6,300		1,585,457
HGP activities	519,140	⁹ 55,000		464,140		519,140
Total	\$ 2,104,597	\$ 55,000	\$ 1,579,157	\$ 470,440		\$ 2,104,597
Chemical Review (Monitoring Compliance)						
Pesticides Program	1,499,850					
Veterinary Medicines Program	818,523					
Chemistry and Residues Evaluation	536,908					
Advice from agencies	1,884,710					
Total	\$ 4,739,991			\$ 4,739,991		\$ 4,739,991
Quality Assurance						
Agricultural AERP	450,000			450,000		450,000
Veterinary AERP	231,620			231,620		231,620
Manufacturing Licence Scheme	733,241	119,160		614,081		733,241
Ag Actives Quality Assurance	100,000			100,000		100,000
Quality Assurance Support	190,264			¹⁰ 190,264		190,264
Total	\$ 1,705,125	\$ 119,160		\$ 1,585,965		\$ 1,705,125
Corporate costs¹¹	3,011,808		112,437	1,999,371	¹² 900,000	3,011,808
Total all activities	\$ 23,265,786	\$ 5,386,020	\$ 3,030,385	\$ 13,949,381	\$ 900,000	\$ 23,265,786
Add: Reconstitution of reserve	1,000,000			1,000,000		1,000,000
PROJECTED TOTAL	\$ 24,265,786	\$ 5,386,020	\$ 3,030,385	\$ 14,949,381	\$ 900,000	\$ 24,265,786

⁸ Estimated costs for consents to import are recovered through the levy – see discussion below

⁹ Includes administrative costs for HGP new licences and renewals

¹⁰ QA support activities relate to APVMA corporate services e.g. corporate governance, international work.

¹¹ Refer section 3.4 for rationale for distribution. Includes corporate governance, international work, expert advice to government, communication with stakeholder groups and strategic initiatives

¹² Projected revenue from interest, minor use appropriation and other revenue

Reconstitution of the APVMA's reserves

Largely as a result of the drought and the reduction in the levy rate in 2000, the APVMA has experienced declining revenue. This has come at a time when the Authority has taken on additional program delivery activities and absorbed large increases in non-discretionary expenditure items such as insurance and superannuation.

As highlighted in the April 2004 CRIS on the proposed interim cost recovery measure for FY2004-05, this has resulted in a significant decline in the APVMA's reserves.

The reserve provides protection to the APVMA in the event of revenue fluctuations. As part of the Fees Review, the then NRA Board considered what was a prudent reserve for the APVMA to maintain. The Board determined, in view of the new cost recovery arrangements, that the reserve should be limited to \$4.5 million, comprising:

- \$3.5 million general reserve, to provide protection against major downturns in sales. This reserve equates to approximately 3 month's operating costs;
- \$500,000 legal contingency, required in the event of litigation; and
- \$500,000 capital expenditure provision.

This reserve has largely been eroded as a result of the drought and delays associated with the introduction of new cost recovery arrangements.

It is proposed to adjust the levy rate to encompass the requirement to reconstitute the APVMA's financial reserves.

Application fees

It is recommended that 40% of the cost of assessments is recovered through application fees. The recommended fee structure is to reduce the number of categories to a total of 24 categories of application to replace the 50 provided in the previous fee structure (see Appendix 2). This will significantly reduce the number of application categories.

- In the new fee structure, there will be 17 fixed cost application fee categories.
- Five additional application categories are "modular" categories that provide flexibility for applications that do not fit the "standard" fixed cost categories. To ensure that the fee will only include the specific evaluation and administration costs incurred by APVMA for that product, the application fee will be calculated from the sum of the individual fees for the assessment modules used.
- The remaining two categories (emergency permits and variations of a minor nature where the change has been requested by the APVMA) will not attract a fee.
- There are no longer any specific application categories relating to secondary applications (6 categories in the existing system). Instead, in the proposed system, these applications would fall into the categories where fees are charged on a modular basis.
- The 18 specific application categories for veterinary chemical products in the existing system have been removed.

In most cases, current and proposed categories cannot be directly compared. Many of the current application categories relate to a wide range of product types, requiring a wide range of assessments under the one category. Under the proposed structure, the different product

applications (which are currently within the same category and currently have the same fee) will be charged appropriately for the level of assessment required. This may result in many combinations of modules and therefore a range of fees for applications that were previously in the same category.

Factors such as whether the active constituent has previously been approved and the level of assessment required will determine the application category and the resulting fee.

Annual Fee

In addition to the costs of investigation and enforcement, it is considered appropriate to factor the costs of several other specific activities into the annual fee, as these are also activities that potentially relate to all registered products but for which a levy based on sales would not be appropriate.

Costs (totalling \$3,030,385¹³) incurred by the APVMA that would be factored into an annual fee include the costs associated with:

- Category 38 applications;
- Investigation, enforcement and support; and
- The costs of maintaining the product on the register.

Category 38 applications are applications where the APVMA requests a change of an administrative nature to a product label. Under the existing cost recovery arrangements, no fee is charged for these applications. In the proposed new application fee category, it is also proposed to have a nil fee for the equivalent category (Category 13).

The APVMA maintains a register of products and active constituents and it is proposed to include the administrative cost of maintaining a product on the register in the annual fee.

While it is difficult to forecast how many products will be on the register following the introduction of the new cost recovery arrangements, it was estimated that an annual fee of \$390 would be sufficient to recover the costs of the above 3 items.

¹³ Refer Table 8

Levy

Levy Based Activities

If there were not to be any distribution of the costs of the evaluation of applications between the application fees and the levy and the full costs were born solely by the applicant, the costs of only the following activities would be recovered through the levy:

Consents to Import:	\$6,300
HGP Audits:	\$464,140
AERP (ag & vet)	\$681,620
MLS	\$614,081
Ag actives QA	\$100,000
QA support	\$190,264
Corporate costs	\$1,999,371
Chemical review	\$4,739,991
TOTAL:	\$8,795,767¹⁴

Consent to Import Certificate

The cost of evaluating and issuing Consent to Import Certificates will be recovered through the levy as a fee would be counter-productive. If a fee for a Consent to Import Certificate were to be charged¹⁵, the APVMA would lose valuable information on what unapproved active constituents and unregistered products are entering Australia. This would subsequently hinder the effectiveness of APVMA compliance activities aimed at preventing the importation of unapproved or unregistered active constituents or products.

Veterinary Manufacturers Licensing Scheme

Currently, the total fee payable for the GMP licence is \$6,000, payable in instalments that are prescribed, but which are determined as a function of the category of veterinary product and the total annual notional wholesale value of the products manufactured by the licence holder at the site. Instalments range from \$150 - \$1,500 per annum and cease once the total fee of \$6,000 has been paid. In the 2003-04 financial year, \$156,000 was received in licence fees.

The annual cost of the Veterinary Manufacturers Licensing Scheme (relating to initial assessments of licence applications and consideration of initial and subsequent audit reports) is estimated to be \$733,241 (refer Table 8). While the cost of this scheme would normally be considered as part of the CRIS,, the existing fee structure was not reviewed in this CRIS as the Department has been advised that changes to the fee structure would constitute an acquisition of property which may offend against s.51 (xxxi) of the Constitution unless compensation was paid to existing licence holders.

Based on the existing licence fee structure, it is predicted that annual revenue from licence fees will be \$119,160 following the introduction of the proposed new cost recovery arrangements. Consequently, \$614,081 of the cost of the scheme will be recovered through the levy.

¹⁴ Refer Table 8

¹⁵ As was proposed in the December 2003 CRIS.

It is recommended that the veterinary manufacturers licensing scheme is specifically included in the terms of reference of the review of the new cost recovery arrangements in 2007-08 (see Section 6).

Corporate Costs

Corporate costs include corporate governance, international work, expert advice to government, communication with stakeholder groups and strategic initiatives. These activities are usually related to the APVMA's key activities, for example: international work focuses largely on promoting, through the OECD, harmonisation in reporting and assessment.

Base Effective Levy Rate

In the case where these identified costs (of registration and approval) were not to be recovered from the levy, but the reserve was to be reconstituted, a base effective levy rate of 0.40% would be required.

Tiered Levy Structures

A tiered levy model has been developed to increase the level of contribution by low-sales products to recover the shortfall in the cost of assessing applications whilst reducing the contribution by high sales products to more reasonable levels. The underlying policy basis of any tiered levy structure is that as the level of product sales increases, the effective levy rate becomes progressively closer to the base effective levy rate of 0.40%.

The preferred tiered levy model is as follows (including the reconstitution of the reserve)

- 0.90% levy rate up to \$1,000,000 product sales
- 0.55% levy rate for additional sales from \$1,000,001 to \$5,000,000
- 0.40% for additional sales above \$5,000,000

Under this model, for products with sales of greater than \$1 million but less than \$5 million, the first \$1 million of sales would be charged at 0.90% and additional sales above this threshold would be charged at 0.55%. For products with sales above \$5 million, the first \$1 million would be charged at 0.90%, a levy rate of 0.55% applies to the next \$4 million and additional sales above \$5 million are charged at 0.40%.

The following table illustrates the annual fee and levy payable at various levels of sales:

Table 9: Total Contributions by Product

Product Sales \$	Annual Fee plus Levy per Product	Levy per Product	Effective Levy Rate ¹⁶
\$0	\$390	\$0	0.00%
\$10,000	\$480	\$90	0.90%
\$25,000	\$615	\$225	0.90%
\$50,000	\$840	\$450	0.90%
\$100,000	\$1,290	\$900	0.90%
\$500,000	\$4,890	\$4,500	0.90%
\$1,000,000	\$9,390	\$9,000	0.90%
\$2,000,000	\$14,890	\$14,500	0.73%
\$3,000,000	\$20,390	\$20,000	0.67%
\$5,000,000	\$31,390	\$31,000	0.62%
\$10,000,000	\$51,390	\$51,000	0.51%
\$20,000,000	\$91,390	\$91,000	0.46%
\$30,000,000	\$131,390	\$131,000	0.44%
\$40,000,000	\$171,390	\$171,000	0.43%
\$50,000,000	\$211,390	\$211,000	0.42%

However, there will still be a large number of products that will not repay the cost of assessment, as shown in the Table 10.

Table 10: Average Annual Contribution per Product as a Percentage of the Shortfall in the Cost of Assessment of Applications¹⁷

Average Annual Contribution as % of Shortfall	Level of Cost Recovery through Fee							
	20%	30%	40%	50%	60%	70%	80%	90%
0%	3	3	-	-	-	-	-	-
1% - <10%	80	76	72	65	62	52	42	28
10% - <20%	13	16	19	24	22	22	20	15
20% - <40%	19	18	20	15	13	17	22	19
40% - <60%	8	7	7	9	14	8	7	12
60% - <100%	3	6	6	10	8	14	13	16
100% - <200%	1	1	3	4	7	11	15	14
200% or greater	-	-	-	-	1	3	8	23

¹⁶ Effective Levy Rate is the total levy paid redistributed over total sales per product.

¹⁷ Based on the following parameters of the existing cost recovery model: Annual Fee of \$390; 3 Tiered Levy at the following rates: 0.90%, 0.55% & 0.40% with tiers at 0 - \$1 million, 1 million - \$5 million & >\$5 million.

While there will still be a large number of products that will not repay the cost of assessment, in comparison to the cost recovery model in Table 6¹⁸ this model increases the level of repayment by low sales products and decreases the level of overpayment by high sales products.

Table 11. Comparison of Shortfall Figures for Categories 1, 12, 14, 15, & 28 with Application Fees set at Nominal rate of 40% of Cost

Average payments as % of shortfall	Existing Model ¹⁹	December 2003 Model	Proposed Model
0%	7	8	-
1% - <10%	68	74	72
10% - <20%	20	12	19
20% - <40%	22	18	20
40% - <60%	6	5	7
60% - <100%	4	5	6
100% - <200%	-	4	3
200% or greater	-	1	-

¹⁸ December 2003 CRIS proposed model.

¹⁹ An analysis of the existing cost recovery model is provided in Appendix 1.

4 PROPOSED REVISED COST RECOVERY FRAMEWORK

4.1 Proposed Revised Cost Recovery Framework

1. Application fees

Application fee categories and modular fee categories are listed in Appendix 2 and Appendix 3. A comparison of current and proposed fees for modules has been provided at Appendix 4.

2. Permit fees

There will be a fee for all permits except emergency use permits and some permits where a government agency is the permit holder:

- A nominal fee of \$320 will be payable by all applicants for minor use permits, to cover the administrative costs of the application.
- Research permits will be 40% cost recovered (i.e. Category 23 – modular assessment).
- Government agencies will be required to pay a fee for permits where this is associated with a use that provides a significant commercial benefit to that organisation (or an agent of that organisation), but that there will be an exemption from payment of fees where the Australian, State or Territory Governments apply for a permit in support of their core business.

3. Annual fee of \$390

An annual fee of \$390 will maintain product registration for a financial year.

4. Financial year basis

In recognition that many Australian companies prepare financial statements on a financial year basis, the levy will be based on financial years (not calendar years as currently occurs). The change to a financial year basis will apply for the 2004-2005 financial year (the levy will fall due on 31 December 2005) and there will be special provisions for the first six months of 2004. Further information on this is provided later in the CRIS.

5. No cap on the levy or minimum sales levy volume

The existing cap of \$25,000 and minimum sales levy volume of \$100,000 per product will be removed.

6. Tiered levy rate structure

- Levy rate of 0.90% on product sales up to \$1 million
- For products with sales between \$1 million and \$5 million, a levy rate of 0.90% on the first \$1 million in product sales, then a levy rate of 0.55% on the remaining product sales above \$1 million

- For products with sales greater than \$5 million, a levy rate of 0.90% on the first \$1 million in product sales, then a levy rate of 0.55% on \$4 million product sales, then a levy rate of 0.40% on the remaining product sales above \$5 million.

The change to the levy will be implemented for the 2005-2006 financial year. The provision for the levy to be paid in instalments will be retained (a timetable is provided later in the CRIS at Section 5).

7. Fees for administrative services such as provision of database information and export and import certificates

With the exception of a Consent to Import, full cost recovery will be applied to administrative services, including:

- Certificates of Export:
 - Standard format \$115
 - Non-standard format \$210
 - Plus additional \$20 for DFAT fee if required.
 - Identical duplicate certificates will be provided free of charge except where an original Department of Foreign Affairs and Trade (DFAT) verification is requested where a \$20 (DFAT) fee will apply. Where any change to the certificate is required, the full fee will be payable.
- provision of database information.

A comparison of current and proposed service fees is provided at Appendix 4.

8. Manufacturers' Licensing Scheme (MLS)

A fee of \$6,000, paid in instalments.

9. Penalty for understating the leviable value of disposals

The penalty for providing information that results in understating the leviable value of disposals to the APVMA will be \$100 or 25% of the unpaid levy (whichever is the greater).

- The penalty will be incurred by the person who understated the leviable value of disposals in a levy declaration;

4.2 Impact of the Proposed Cost Recovery Framework

In general, the individual contribution per product will be increased, although there will be some products where the annual contribution will decrease, i.e. products with sales that were at the lower end of a previous sales category for the Registration Renewal Fee.

Table 12: Comparison of Individual Contributions per Product under Cost Recovery Models

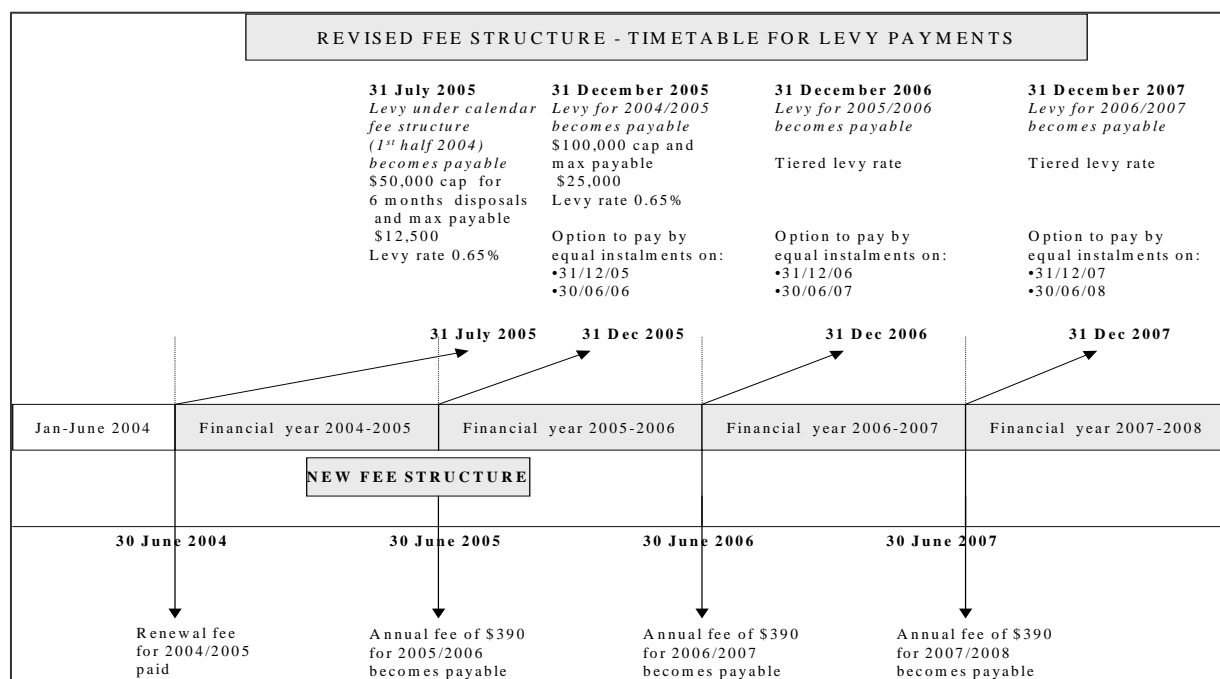
Sales per Product (\$)	Existing Model \$	December 2003 Model \$	Proposed Model \$
\$0	200	180	390
\$1 – \$10,000	200 or 300	180	390 - 480
\$10,001 – \$25,000	600	180 - 185	480 - 615
\$25,001 - \$100,000	1,000	185 - 740	615 - 1,290
\$500,000	4,250	3,700	4,890
\$1,000,000	7,500	7,400	9,390
\$2,000,000	14,000	14,800	14,890
\$5,000,000	26,000	37,000	31,390
\$10,000,000	26,000	74,000	51,390
\$20,000,000	26,000	148,000	91,390
\$50,000,000	26,000	370,000	211,390

5 IMPLEMENTATION TIMETABLE

It is proposed to introduce the necessary amendment Bill in the coming Autumn 2005 Sittings of Parliament and for the amending Bill to commence on 1 June 2005. The provisions of the Bill would be effective from the start of the 2005-2006 financial year and revised application fees would come into effect immediately for any new applications. However, because levy payments become due 6 months after the year to which they apply, it will take eighteen months for all the changes to flow through and completely affect payments from registrants.

- The levy will be calculated from disposals during the financial year, rather than a calendar year, for the 2004-2005 financial year and subsequent years.
- The levy for 2004-2005 will become payable on 31 December 2005²⁰ (based on current levy parameters).
- The levy for the 1st half of 2004 (January – June) will be payable on 31 July 2005 and levy arrangements will be adjusted to reflect that this is a 6 month period rather than a year (i.e. the minimum sales volume will be \$50,000 and the maximum levy payable will be \$12,500).
- The first payments based on the new levy rates and the removal of the minimum sales volume and levy cap will be those that become payable on 31 December 2006 (for the 2005-2006 financial year).
- From June 2005, registrants will pay an Annual Fee of \$390, rather than the annual registration renewal fee.

As well, the APVMA has the capacity to vary the above-prescribed dates for payment pursuant to the provisions of paragraph 6(1)(b) of the Collection of Levy Act. However, the existing arrangements for paying the levy in instalments will continue to apply, with the exception of the payment of levy for the 1st half of 2004 (payable 31 July 2005).



The following diagram and table show the timetable for the transition to the new levy arrangements.

Table 13: Timetable for the transition to the new levy arrangements

TIMETABLE FOR PAYMENTS						
Date payment falls due	Relevant time period	Annual Fee	Levy rate %	\$100,000 minimum sales volume	Maximum levy payable	
<i>30 June 2005</i>	2005-2006	\$390				
<i>31 July 2005</i>	1 st half 2004 (Jan-June)	N/A (Renewal fee for 2004-2005 previously paid 30 June 2004)	0.65	Yes (\$50,000 over 6 months)	\$12,500	
<i>31 December 2005</i>	2004-2005 financial year	N/A	0.65	Yes	\$25,000	
<i>30 June 2006</i>	2006-2007	\$390				
<i>31 December 2006</i>	2005-2006	N/A	tiered	No	No cap	

TIMETABLE FOR PAYMENTS (IF PAID IN INSTALMENTS - OPTIONAL)						
Date payment falls due	Relevant time Period	Annual Fee	Levy rate %	\$100,000 minimum sales volume	Maximum levy payable	Proportion of total levy
<i>30 June 2005</i>	2005-2006	\$390				
<i>31 July 2005</i>	1 st half 2004 (Jan-June)	N/A (Renewal fee for 2004-2005 previously paid 30 June 2004)	0.65	Yes (\$50,000 over 6 months)	\$12,500	
<i>31 December 2005</i>	2004-2005 financial year	N/A	0.65	Yes	\$25,000	Half 2004-2005 levy
<i>30 June 2006</i>	2004-2005 financial year	N/A	0.65	Yes		Half 2004-2005 levy
	2006-2007	\$390				
<i>31 December 2006</i>	2005-2006	N/A	tiered	No	No cap	Half 2005-2006 levy
<i>30 June 2007</i>	2005-2006 financial year	N/A (previously paid 30 June 2005)	tiered	No	No cap	Half 2005-2006 levy
	2007-2008	\$390				

6 REVIEW

6.1 What Mechanisms, Including Consultation, Should be Used for Ongoing Monitoring of the Efficiency and Effectiveness of the Cost Recovery Arrangements?

The APVMA Board is responsible under Section 9 of the *Commonwealth Authorities and Companies Act 1997* for the preparation of an Annual Report. This contains financial statements that provide some information on the operation of the cost recovery arrangements.

Formal consultation with stakeholders will continue to be conducted through the Industry Liaison Committee, the main consultative forum between the APVMA and peak chemical organisations representing registrants, which meets three times per year.

6.2 How long before the cost recovery arrangements should be reviewed again?

A review will be conducted in 2007-2008 as part of the review of the cost recovery arrangements of the Agriculture, Fisheries and Forestry portfolio under the agreed review schedule outlined in the Government's cost recovery policy (www.finance.gov.au/finframework/fc_2002_02.html).

6.3 Specific issues identified for review

It is recommended that the veterinary manufacturers licensing scheme is specifically included in the terms of reference of the review of the new cost recovery arrangements in 2007-08.

7 CONSULTATION

7.1 Consultation

Following earlier consultation, which included a draft CRIS released for public comment in December 2003 and an industry workshop in August 2004, a revised draft CRIS was released for public comment on 17 November 2004.

Activities to achieve wide distribution of the CRIS and to ensure that stakeholders were aware of the opportunity to comment on the proposed changes to the cost recovery arrangements for the APVMA included:

- A media release on 17 November 2004 by Senator the Hon Richard Colbeck, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry, announcing the release of the revised draft CRIS and providing information on how to access the CRIS and submit comments on the CRIS;
- The draft CRIS was made available on the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) website on 17 November 2004;
- DAFF emailed copies of the CRIS to key stakeholder groups, to individuals or organisations that had previously made submissions on earlier CRIS's and to members of the APVMA Community Consultative Committee and the APVMA Industry Liaison Committee;
- DAFF wrote to all current registrants and approval holders informing them of the release of the revised draft CRIS and providing information on how to access the CRIS and submit comments on the CRIS;
- A link to the relevant DAFF website was provided on the APVMA website and an alert was provided through the APVMA's electronic news bulletin.

The closing date for comments on the draft CRIS was 16 December 2004.

7.2 Summary of Submissions

16 submissions were received on the revised draft CRIS (see list at Appendix 7). In addition, several State and Territory primary industries or agriculture departments provided comments.

While several submissions commented favourably on the increased level of analysis in the revised draft CRIS, they also considered that the substance of the proposed model remained unchanged from the previous model (outlined in the December 2003 CRIS), particularly in relation to the proposed split between application fees and the levy to recover the cost of assessment of applications and the retention of the proposal to remove the cap on the levy. The tiered levy was only specifically addressed in a few submissions.

Submissions sought further consideration or clarification on several issues, including the definition of minor use, whether government agencies would be charged a fee for research permits, and the procedure to be followed once the APVMA reserves are reconstituted. Other specific issues raised in submissions included:

- Annual fee;
- APVMA efficiency; and
- CRIS assumptions and analysis.

Annual fee

Several submissions opposed the introduction of the proposed annual fee and proposed alternative models.

- One submission recommended that the previously proposed Minimum Levy (set at \$200) be retained in the current model instead of the annual fee and the levy rates in the tiered levy be increased to compensate for this.
- Another submission expressed concern that the fee may result in some products being lost from the market, potentially disadvantaging users, and suggested that the costs of investigation, enforcement and support activities could be included in the levy.
- A third submission considered that re-registration costs should be minimal for nil sales or low volume products and should not include the cost of any compliance activities.

Submissions also commented on the potential impact of the annual fee.

- It was predicted that the annual fee would result in the loss of many silent, unused registrations of products, such as reserve products that could be used if alternatives are withdrawn from the market.
- In relation to pool and spa hypochlorites, it was predicted that the competitive nature of the pool business would negate the possibility of passing the increased cost (of the annual fee in comparison to the registration renewal fee) on to the retail trade.

Application fee

A number of submissions opposed recovery of 40% of the cost of assessments through the application fee and instead supported application fees based on 100% cost recovery through the fee. However, the proposal was supported in other submissions and two submissions considered that specific proposed fees were too high.

The arguments expressed in submissions against the proposed fee structure include that:

- The cost recovery arrangements were considered to be inconsistent with the *Commonwealth Cost Recovery Guidelines for Regulatory Agencies* and the principles of “beneficiary pays”, efficiency and equity that underpin the Commonwealth’s cost recovery policy;
- The arrangements were considered to be inconsistent with the recommendations of the National Competition Policy Review with regard to the imposition of approval and registration fees that are cost reflective;
- The proposed cost recovery model would result in certain products paying fees and levies that would not reflect their respective burden on the regulatory regime, leading to cross subsidisation between products, participants and industry sectors, including from the agricultural chemicals sector to the veterinary medicines sector;
- The proposed cost recovery model does not reflect the benefits that registrants will receive under the data protection legislation introduced as part of the AUSFTA;
- It was considered that the CRIS, in concluding that the proposed fee structure will encourage innovation, demonstrated a lack of understanding of the factors influencing innovation;
- Recovery of the shortfall through the levy would lead to an increase in chemical production costs that farmers would not be able to recover in the price of farm outputs; and

- It was considered that some strategic APVMA projects are in the public benefit and therefore should receive Government funding.

In order to address the problem of encouraging the registration of crucial low sales products, one submission proposed an orphan products scheme similar to the Therapeutic Goods Administration scheme.

The issue of assessment times was also raised in the context of modular application fee categories.

Proposed removal of the cap on the levy

The submissions that opposed the proposed split between application fees and the levy to recover the cost of assessment of applications generally also recommended a cap on the levy of up to \$100,000 per product. One submission proposed, as a second option, a levy that is capped per company.

However, other submissions supported the abolition of the levy cap.

The arguments expressed in submissions against the proposed removal of the cap on the levy include that:

- the *Commonwealth Cost Recovery Guidelines for Regulatory Agencies* noted that there is a point beyond which the cost of regulation does not increase and therefore a cap on the sales levy is a tool to manage this finite cost;
- it was predicted that an open ended cost recovery mechanism, such as an uncapped sales levy, would not drive cost efficiencies or productivity gains within the regulator;
- it was considered that it introduces an open-ended wholesale tax on agvet chemical sales; and
- submissions argued that there was no correlation between the total amount of levies payable to the APVMA in respect of a product and the regulatory cost incurred by the APVMA in relation that product
 - one submission suggested that the likelihood of adverse reports increase with hazard level rather than sales.

Tiered levy

While few submissions commented specifically on the proposal for a tiered levy to replace a flat rate levy, one submission supported the proposal on the grounds that it would restore a more equitable balance between the respective contributions of low-sales products and those of large-sales products.

However, other submissions considered that the proposal introduces a wholesale sales tax on agvet chemical that would be contrary to the Government's New Taxation System and would introduce additional levy/tax compliance costs for both the APVMA and agvet chemical companies.

One submission recommended a single per cent levy (in conjunction with a cap on the levy).

Minor use permit fee

In comparison to the previous consultation on the cost recovery model outlined in the December 2003 CRIS, fewer submissions were received from horticultural industry organisations in relation to minor use permits.

The submissions that were received on the November 2004 CRIS expressed a range of views in relation to the proposed nominal fee for minor use permits.

- One submission accepted the proposed CRIS model on the basis that the \$320 nominal fee was the only fee payable for a minor use permit.
- Another submission stated that it could support a reduced fee specifically targeted to applications for the registration of minor uses, but considered that product liability and expected economic return were more significant obstacles to the registration of minor uses than APVMA fees.
- While not explicitly opposing the proposal, one submission discussed concerns relating to the potential impact of the fee. In the context of encouraging consolidated applications rather than individual permit requests, the submission advocated fee exemptions for appropriate permit holders (such as representative industry bodies).
- One submission considered that it was inappropriate cross-subsidisation with no benefit to registrants of unrelated products and called for government funding similar to the USA IR4 program.
- One submission objected to the proposed removal of the exemption on the grounds that the revenue gained by the APVMA would be minimal relative to the adverse affect on horticultural industries.

Several submissions suggested that it may be timely to revisit the issue of the definition of minor crops and minor uses.

Research permit fees

There were a few comments on the proposed fee for research permits.

- One submission expressed concern that there would be a significant fee increase for grower organisations requiring a full research permit to undertake grower trials (i.e. where a registration is deemed to be a major use) and requested a reconsideration of the proposed fee arrangements for research permits, particularly for grower organisations;
- It was also predicted that the cost of research permits could increase significantly and that this would affect the amount and cost of research performed by government organisations.

Reconstitution of the APVMA's reserves

Several submissions considered that the forward estimates in the CRIS were conservative because they were not based on recent figures and predicted that the APVMA is likely to reach its targeted equity position ahead of the CRIS projection of 3 years. They recommended that the next review of the APVMA's cost recovery arrangements be initiated when the APVMA recoups its \$4.5million equity position or no later than two years, whichever comes first.

APVMA efficiency

A few submissions expressed concern about the APVMA's efficiency and queried the estimates of the APVMA's projected expenditure. One submission called for a registration model that delivered a "good Holden" rather than a "gold plated Rolls Royce".

As noted in discussing levy design, several submissions expressed concern that an open-ended levy would not foster efficiency.

CRIS assumptions and analysis

Several submissions queried assumptions made in the CRIS or considered that further analysis was required on specific issues.

- Some considered that costs should not be shared equally between the agricultural and veterinary chemical sectors.
- One submission requested further analysis of products with sales of less than \$25,000 per annum to establish whether an alternate regulatory approach may be appropriate for some of these products.
- As noted previously, several submissions considered that further analysis was required on the impact of data protection provisions.
 - One submission also questioned the assumption in the discussion on data protection that the transfer of new innovation into Australia occurs significantly later than in primary markets and that costs have been recovered in primary markets by the time the product enters the Australian market.
- Several submissions queried the assumptions that 40% cost recovery through application fees will encourage innovation and that higher sales are directly proportional to regulatory effort.

7.3 Certification

I, Roland Joseph Smith, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, certify that this CRIS properly identifies the objectives and functions of the Authority and that, in its preparation, the Commonwealth Cost Recovery Guidelines for Regulatory Agencies have been adequately applied.

RJ Smith
Chief Executive Officer
2 March 2005

Appendix 1: ANALYSIS OF EXISTING COST RECOVERY MODEL

Average Annual Contribution per Product as a Percentage of the Shortfall in the Cost of Assessment of Applications (Same conditions as existing Model: Flat levy rate 0.65%, Threshold of \$100,000 product sales and cap on levy of \$25,000)²¹

Average Annual Contribution as % of Shortfall	Level of Cost Recovery through Fee							
	20%	30%	40%	50%	60%	70%	80%	90%
0%	22	7	7	3	3	-	-	-
1% - <10%	67	75	68	65	59	55	41	28
10% - <20%	15	18	20	22	27	21	24	16
20% - <40%	15	18	22	21	15	19	25	21
40% - <60%	6	7	6	7	13	13	6	11
60% - <100%	2	2	4	7	7	10	16	15
100% - <200%	-	-	-	2	3	9	12	21
200% or greater	-	-	-	-	-	-	3	15

It can be seen in this table (based on the application data sampled) that most of the products examined would not repay the shortfall under the existing model (the average level of cost recovery through application fees in the existing model has been estimated to be 30%) and that the model is unlikely to result in overpayment of the shortfall in the cost of any assessments in any one year (given the levy cap of \$26,000).

Manipulation of the level of cost recovery through application fees does not address this. Even if the level of cost recovery through the application fee is raised to 60%, more than half the products examined would never repay the shortfall.

²¹ Based on cost of assessments for Cat 1, 12, 14, 15 and 28 finalised during the period 1997-2000 where the product maintained registration for the period 2001-2003

Appendix 2: PROPOSED APVMA APPLICATION FEE CATEGORIES

It is proposed that, where necessary, further information relating to the following application categories and to the determination of the appropriate application category will be provided in the relevant regulations or in legislative instruments.

Table of fees and assessment periods

Item	Description of application	Period	Fee
Application for approval of active constituent/s contained in a product, registration of the product and approval of the product label/s			
1.	Application for approval of new active constituent/s contained in a product, registration of the associated product and approval of the product label requiring a full ²² assessment of the active/s and product.	15 months	\$48,860
2.	Application for approval of new active constituent/s contained in a product, registration of the associated product and approval of the product label other than as described in 1.	The modular assessment period	The modular assessment fee
Application for registration of a product containing approved active constituent/s and approval of the product label			
3.	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) there is no registered product containing the active/s; and (b) a full ²³ assessment of the product is required.	15 months	\$31,750
4.	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) there is a registered product containing the active/s; and (b) the product is to be used on a major food crop, where there are no relevant MRLs and drug or poison scheduling is required.	15 months	\$21,210
5.	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) the product is similar to a registered product; and (b) chemistry and manufacture, efficacy and target species safety data is the only data required to demonstrate the similarity of the product to the registered product.	5 months	\$3,300
6.	Application for registration of a product containing approved active constituent/s and approval of the product label if: (a) the product is closely similar to a registered product; and (b) efficacy and safety data is NOT required to demonstrate the similarity of the product to the registered product; and (c) chemistry and manufacture data is required.	5 months	\$2,245

²² A full assessment for this item is equivalent to the following Schedule 7 modules: 1, 2.1, 3.1, 4, 5.1, 6.1, 7.1, 8.1, 11.1 and 12.

²³ A full assessment for this item is equivalent to the following Schedule 7 modules: 1, 2.3, 3.3, 4, 5.1, 6.1, 7.1, 8.1, 11.1 and 12.

7.	Application for registration of a chemical product containing approved active constituent/s and approval of the product label if: (a) the product is closely similar to a registered chemical product; and (b) efficacy and safety data is NOT required to demonstrate the similarity of the product to the registered product; and (c) chemistry and manufacture data is NOT required.	3 months	\$600
8.	Application for registration of a chemical product containing approved active constituent/s and approval of the product label if: (a) the product is the same as a registered chemical product; and (b) the product is to be registered with a different product name.	3 months	\$540
9.	Application for a listed registration of a chemical product containing approved active constituents and approval of the product label for which an established standard has been approved in accordance with s.56D of the Agvet Code.	3 months	\$495
10.	Application for registration of a chemical product containing approved active constituents (or an active for which the APVMA has received an application for approval) and approval of the product label for all situations other than as described in 3-9.	The modular assessment period	The modular assessment fee

Application to vary a registration or label approval			
11.	Application to vary particulars or conditions of registration and/or label approval where the variation is to extend the use of the product to a major new food-crop.	8 months	\$14,260
12.	Application to vary particulars or conditions of registration and/or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required.	3 months	\$560
13.	Application to vary particulars or conditions of registration or listed registration and/or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA.	3 months	nil fee
14.	Application to vary particulars or conditions of registration or listed registration and/or label approval if the application is not of a kind described in 11 -13.	The modular assessment period	The modular assessment fee

Application for approval of an active constituent			
15.	Application for approval of an active constituent requiring a full assessment.	12 months	\$23,430
16.	Application for approval of an active constituent requiring a toxicological assessment other than as described in 15.	8 months	\$4,025
17.	Application for approval of an active constituent other than as described in 15 or 16.	5 months	\$1,435

Application for variation to an approved active constituent			
18.	Application to vary particulars or conditions of an approved active constituent.	5 months	\$915

Application for a permit			
19.	Application for a permit to possess or supply, <u>other than for use in Australia</u> , an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product.	3 months	\$320
20.	Application for a permit where a previous assessment remains valid and no data of a technical nature is required.	3 months	\$320
21.	Application for a permit where the proposed use is a minor use.	The modular assessment period	\$320
22.	Application for a permit in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an <u>emergency use</u> .	Not applicable	nil fee
23.	Application for a permit in respect of a chemical product or an active constituent if the application is not of a kind referred to in items 19 to 21.	The modular assessment period	The modular assessment fee

Other applications			
24.	Any other assessment of a technical nature for approval, registration or a permit not of a kind referred to in items 1 - 23, including assessment of a <u>protocol</u> designed to generate data to meet APVMA 'Requirements and Guidelines'.	The modular assessment period	The modular assessment fee

Appendix 3: MODULAR FEES AND ASSESSMENT PERIODS

Item	Module	Period ²⁴	Fee ²⁵
1.	Screening		\$460
2.1	Chemistry – Level 1	12 months	\$2,960
2.2	Chemistry – Level 2	8 months	\$2,025
2.3	Chemistry – Level 3	5 months	\$935
2.4	Chemistry – Level 4	3 months	\$180
3.1	Toxicology – Level 1	12 months	\$17,720
3.2	Toxicology – Level 2	8 months	\$13,290
3.3	Toxicology – Level 3	4 months	\$2,635
4.	Toxicology – <i>Scheduling</i>	12 months	\$3,380
5.1	Residues – Level 1	12 months	\$5,085
5.2	Residues – Level 2 (Registration only)	6 months	\$4,330
5.3	Residues – Level 3 (Permit only)	6 months	\$2,265
5.4	Residues – Level 4 (Registration only)	3 months	\$2,025
5.5	Residues – Level 5 (Permit only)	3 months	\$1,070
6.1	OH&S – Level 1	12 months	\$3,920
6.2	OH&S – Level 2	6 months	\$2,635
6.3	OH&S – Level 3	4 months	\$1,305
7.1	Environment – Level 1	12 months	\$11,460
7.2	Environment – Level 2	6 months	\$2,960
7.3	Environment – Level 3	4 months	\$565
8.1	Efficacy and Safety - Level 1	5 months	\$1,695
8.2	Efficacy and Safety - Level 2	4 months	\$680
8.3	Efficacy and Safety - Level 3	3 months	\$455
9.	Non-food Trade	5 months	\$1,070
10.1	Special Data – Level 1	12 months	nil fee
10.2	Special Data – Level 2	6 months	nil fee
10.3	<i>Any other assessment</i>	6 months	nil fee
11.1	Finalise - Type 1	3 months	\$2,025
11.2	Finalise - Type 2 [Registration only]	2 months	\$1,070
11.3	Finalise - Type 3 [Permit only]	2 months	\$565
11.4	Finalise - Type 4	2 months	\$145
12.	Data Protection		\$155

²⁴ To calculate the assessment period for the application, add the longest assessment period for items 2-10 to the relevant item 11 assessment period

²⁵ To calculate the fee for the application, total the modular fees for all items

The following provides further detail on the modules. It is proposed that, where necessary, further information relating to the modules and to the determination of the appropriate modules will be provided in the relevant regulations or in legislative instruments.

Module for screening of applications

1. This module covers administrative work, handling and advice at screening for all applications before they are accepted for evaluation.

Modules for assessment of product quality, batch-to-batch consistency and stability

- 2.1 This module covers an application that requires a comprehensive assessment of chemistry and manufacture data for both the active/s and the product.
- 2.2 This module covers an application that requires a reduced assessment of chemistry and manufacture data for the active/s and the product that is not as extensive as the assessment required in 2.1 above.
- 2.3 This module covers an application that requires an assessment of chemistry and manufacture data for the product only.
- 2.4 This module covers an application for a variation to chemistry and manufacture details for the product, or any other application requiring a limited chemistry and manufacture assessment.

Modules for assessment of toxicological hazards and advice of public health standards

- 3.1 This module covers an application that requires a comprehensive assessment of toxicological data for the active/s and the product.
- 3.2 This module covers an application that requires a reduced assessment of toxicological data that is not as extensive as the assessment required in 4.1 above.
- 3.3 This module covers any other application requiring a limited toxicological assessment.
4. This module covers drugs and poisons scheduling.

Modules for assessment of food residue levels and human dietary residue exposure and advice on maximum residue limit standards

- 5.1 This module covers an application that requires a comprehensive assessment of residue data.
- 5.2 This module covers a registration application that requires a reduced assessment of residue data that is not as extensive as the assessment required in 5.1 above.
- 5.3 This module covers a permit application that requires a reduced assessment of residue data that is not as extensive as the assessment required in 5.1 above.
- 5.4 This module covers any other registration application requiring a limited residue assessment.
- 5.5 This module covers any other permit application requiring a limited residue assessment.

Modules for assessment of personal user safety

- 6.1 This module covers an application that requires a comprehensive assessment of occupational health and safety data.
- 6.2 This module covers an application that requires a reduced assessment of occupational health and safety data that is not as extensive as the assessment required in 6.1 above.
- 6.3 This module covers any other application requiring a limited occupational health and safety assessment.

Modules for assessment of environmental safety

- 7.1 This module covers an application that requires a comprehensive assessment of environmental data.
- 7.2 This module covers an application that requires a reduced assessment of environmental data that is not as extensive as the assessment required in 7.1 above.
- 7.3 This module covers any other application requiring a limited environmental safety assessment.

Modules for assessment of label claims and adequacy of label instructions and precautions relating to target species efficacy and safety

- 8.1 This module covers an application that requires an efficacy and safety review carried out on either:
- (a) an agricultural chemical product containing:
 - (i) a new active constituent; or
 - (ii) a new combination of active constituents; or
 - (iii) an existing active constituent/s for use in a new crop or situation; or
 - (iv) a significant new formulation not included in module 8.2; OR
 - (b) a veterinary chemical product for use in/on a food-producing species containing:
 - (i) a new active constituent; or
 - (ii) a new combination of active constituents; or
 - (iii) an existing active constituent/s for use in/on a new food animal
- 8.2 This module covers an application that requires an efficacy and safety review carried out on either:
- (a) an agricultural chemical product when module 8.1 is not justified (for example, an extension of use within the same food group); OR
 - (b) a veterinary chemical product:
 - (i) used on companion animals (dog, cat or horse); or
 - (ii) where extension of use is in/on the same food-producing species; or
 - (iii) where a new formulation for a product for use in/on a food-producing species is not identical, closely similar or similar to a reference product.
- 8.3 This module covers any other application requiring a target species efficacy and/or safety review.

Module for assessment of non-food trade risk

9. This module covers an application requiring assessment of trade risk relating to non-food residue situations eg – fibre residues, presence of disease or seropositive testing to exotic or notifiable disease agents, genetically modified produce.

Modules for assessment of other data

- 10.1 This module covers an application that requires a comprehensive assessment of part 10 special data.
- 10.2 This module covers an application that requires a reduced assessment of part 10 special data that is not as extensive as the assessment required in 10.1 above.
- 10.3 This module covers any other application requiring an assessment of special data such as assessment of product containing a GMO.

Module for administrative and technical steps in public consultation and finalisation of applications

- 11.1 This module covers finalisation of a registration or permit application that requires three or more modular assessments covered in items 2.1 to 10.3 above, except for item 2.4.
- 11.2 This module covers a registration application that requires less than three of the modular assessments covered in items 2.1 to 10.3 above.
- 11.3 This module covers a permit application that requires less than three of the modular assessments covered in items 2.1 to 10.3 above.
- 11.4 This module covers any minor application requiring technical assessment including modular items 2.4.

Module for assigning data protection

12. This module covers administrative and technical steps in assigning protection to relevant data.

Appendix 4: COMPARISON OF CURRENT AND PROPOSED FEE STRUCTURE FOR MODULES AND SERVICES

	Module	Current Fee	Proposed fee
1	Screening	\$620	\$460
2.1	Chemistry – Level 1	No fee	\$2,960
2.2	Chemistry – Level 2	No fee	\$2,025
2.3	Chemistry - Level 3	\$1,030	\$935
2.4	Chemistry - Level 4	\$1,030	\$180
3.1	Toxicology - Level 1	\$9,690	\$17,720
3.2	Toxicology - Level 2	\$5,980	\$13,290
3.3	Toxicology - Level 3	\$2,475	\$2,635
4	Toxicology – <i>Scheduling</i>	No fee	\$3,380
5.1	Residues - Level 1	\$2,475	\$5,085
5.2	Residues - Level 2 (Registration only)	\$2,475	\$4,330
5.3	Residues - Level 3 (Permit only)	\$2,475	\$2,265
5.4	Residues - Level 4 (Registration only)	\$2,475	\$2,025
5.5	Residues - Level 5 (Permit only)	\$2,475	\$1,070
6.1	OH&S – Level 1	\$1,030	\$3,920
6.2	OH&S – Level 2	\$1,030	\$2,635
6.3	OH&S – Level 3	\$1,030	\$1,305
7.1	Environment - Level 1	\$3,095	\$11,460
7.2	Environment - Level 2	\$3,095	\$2,960
7.3	Environment - Level 3	\$3,095	\$565
8.1	Efficacy and Safety - Level 1	\$3,095	\$1,695
8.2	Efficacy and Safety - Level 2	\$2,060	\$680
8.3	Efficacy and Safety - Level 3	\$1,030	\$455
9	Non-Food Trade	No fee	\$1,070
10.1	Special Data – Level 1	No fee	\$0
10.2	Special Data – Level 2	No fee	\$0
10.3	<i>Any other assessment–</i>	No fee	\$0
11.1	Finalise – Type 1	No fee	\$2,025
11.2	Finalise – Type 2 (Registration only)	No fee	\$1,070
11.3	Finalise – Type 3 (Permit only)	No fee	\$565
11.4	Finalise – Type 4	No fee	\$145
12	Data Protection	No fee	\$155

	Service	Current Fee	Proposed fee
	Registration Information		
	Certificates of export (no technical assessment)	\$120	\$115
	Certificates of export (requires technical assessment by an APVMA scientist)	\$120	\$210
	Database information	\$20 per hour	\$90 per hour
	Approved labels	\$20 per hour	\$75 per hour
	MLS		
	GMP licence - APVMA assessment required	\$250 - \$1,500 per year*	\$250 - \$1,500 per year*
	GMP licence - applicant holds a licence from an approved authority	\$150 - \$300 per year*	\$150 - \$300 per year*
	HGP		
	Notification Number Application	\$200	\$275
	Notification Number Renewal	\$200	\$275
	Other Compliance services		
	Consents to Import	no fee	no fee
	Registration Renewal Fee	\$200 - \$1,000 per year	\$0
	Annual Fee	N/A	\$390
	Levy Rate	0.65%	tiered

* Fee ceases when total price equals \$6,000.

Appendix 5: Proposed APVMA Revenue

Fees 100% Cost Recovered

Item	Description	Proposed Fee Implementation 1/7/05	Applications Received Predicted Volume	Predicted Revenue	Levy Revenue Required	Total Revenue	Actual Cost ¹
Application							
7	Registration of product containing approved active. Product similar to registered product, no chemistry and no efficacy data required.	\$600	258	\$154,800	\$0	\$154,800	\$154,800
8	Registration of product containing approved active. Product identical to registered product, other than product name.	\$540	327	\$176,580	\$0	\$176,580	\$176,580
9	Application for a listed registration of a product containing approved active.	\$495	7	\$3,465	\$0	\$3,465	\$3,465
12	Application to vary particulars or conditions of registration and/or label approval if: (a) the variation is to permit a minor change; and (b) no data of a technical nature is required.	\$560	290	\$162,400	\$0	\$162,400	\$162,400
19	Application for a permit to possess or supply, other than for use in Australia, an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product.	\$320	2	\$640	\$0	\$640	\$640
20	Application for a permit where a previous assessment remains valid and no data of a technical nature is required.	\$320	191	\$61,120	\$0	\$61,120	\$61,120
Module							
1	Screening	\$460	1283	\$590,180	\$0	\$590,180	\$590,180
Registration Information							
	Certificates of export (no technical assessment)	\$115	454	\$52,210	\$0	\$52,210	\$52,210
	Certificates of export (requires technical assessment by an APVMA scientist)	\$210	454	\$95,340	\$0	\$95,340	\$95,340
	Database information	\$90	875	\$78,750	\$0	\$78,750	\$78,750
	Approved labels	\$75	875	\$65,625	\$0	\$65,625	\$65,625
	TOTAL FEES 100% COST RECOVERED			\$1,441,110	\$0	\$1,441,110	\$1,441,110

¹ Application fees are based on 40% recovery of the cost of technical evaluations and 100% cost recovery applies for administrative services i.e. screening. Application items 1,3,4,5,6,11,15-18 include a combination of administrative (e.g. screening) and technical activities.

Fees 40% Cost Recovered

Item	Description	Proposed Fee Implementation 1/7/05	Applications Received Predicted Volume	Predicted Revenue	Levy Revenue Required	Total Revenue	Actual Cost ¹
Application							
1	Approval of new active and registration of a product requiring a full assessment.	\$48,860	10	\$488,600	\$726,000	\$1,214,600	\$1,214,600
3	Registration of product containing approved active. First product registration involving active, full product assessment.	\$31,750	2	\$63,500	\$93,870	\$157,370	\$157,370
4	Registration of product containing approved active. New food crop use for active, new MRLs and poison scheduling required.	\$21,210	23	\$487,830	\$715,875	\$1,203,705	\$1,203,705
5	Registration of product containing approved active. Product similar to registered product, chemistry and efficacy data required.	\$3,300	38	\$125,400	\$161,880	\$287,280	\$287,280
6	Registration of product containing approved active. Product similar to registered product, chemistry data required.	\$2,245	40	\$89,800	\$107,100	\$196,900	\$196,900
11	Application to vary particulars or conditions of registration and label approval where the variation is to extend the use of the product to a major new food-crop.	\$14,260	13	\$185,380	\$269,100	\$454,480	\$454,480
15	Application for approval of an active constituent requiring a full assessment.	\$23,430	5	\$117,150	\$175,725	\$292,875	\$292,875
16	Application for approval of an active constituent requiring a toxicological assessment other than as described in 15.	\$4,025	5	\$20,125	\$30,188	\$50,313	\$50,313
17	Application for approval of an active constituent other than as described in 15 or 16.	\$1,435	101	\$144,935	\$217,403	\$362,338	\$362,338
18	Application to vary particulars or conditions of an approved active constituent.	\$915	9	\$8,235	\$12,353	\$20,588	\$20,588
Module							
2.1	Chemistry – Level 1	\$2,960	2	\$5,920	\$8,880	\$14,800	\$14,800
2.2	Chemistry – Level 2	\$2,025	19	\$38,475	\$57,713	\$96,188	\$96,188
2.3	Chemistry – Level 3	\$935	180	\$168,300	\$252,450	\$420,750	\$420,750
2.4	Chemistry – Level 4	\$180	80	\$14,400	\$21,600	\$36,000	\$36,000
3.1	Toxicology – Level 1	\$17,720	3	\$53,160	\$79,740	\$132,900	\$132,900
3.2	Toxicology – Level 2	\$13,290	5	\$66,450	\$99,675	\$166,125	\$166,125
3.3	Toxicology – Level 3	\$2,635	48	\$126,480	\$189,720	\$316,200	\$316,200
4	Toxicology – Scheduling	\$3,380	30	\$101,400	\$152,100	\$253,500	\$253,500
5.1	Residues – Level 1	\$5,085	2	\$10,170	\$15,255	\$25,425	\$25,425
5.2	Residues – Level 2 (Registration only)	\$4,330	17	\$73,610	\$110,415	\$184,025	\$184,025
5.3	Residues – Level 3 (Permit only)	\$2,265	29	\$65,685	\$98,528	\$164,213	\$164,213
5.4	Residues – Level 4 (Registration only)	\$2,025	22	\$44,550	\$66,825	\$111,375	\$111,375
5.5	Residues – Level 5 (Permit only)	\$1,070	12	\$12,840	\$19,260	\$32,100	\$32,100
6.1	OH&S - Level 1	\$3,920	2	\$7,840	\$11,760	\$19,600	\$19,600
6.2	OH&S - Level 2	\$2,635	41	\$108,035	\$162,053	\$270,088	\$270,088
6.3	OH&S - Level 3	\$1,305	28	\$36,540	\$54,810	\$91,350	\$91,350

Item	Description	Proposed Fee Implementation 1/7/05	Applications Received Predicted Volume
7.1	Environment - Level 1	\$11,460	10
7.2	Environment - Level 2	\$2,960	2
7.3	Environment - Level 3	\$565	61
8.1	Efficacy - Level 1	\$1,695	0
8.2	Efficacy - Level 2	\$680	90
8.3	Efficacy - Level 3	\$455	18
9	Non-Food Trade	\$1,070	7
10.1	Special Data – Level 1	Nil	N/A
10.2	Special Data – Level 2	Nil	N/A
10.3	Any other assessment	Nil	N/A
11.1	Finalise - Type 1	\$2,025	59
11.2	Finalise - Type 2 [Registration only]	\$1,070	401
11.3	Finalise - Type 3 [Permit only]	\$565	169
11.4	Finalise - Type 4	\$145	0
12	Data Protection	\$155	439
TOTAL FEES 40% COST RECOVERED			

Item	Description	Proposed Fee Implementation 1/7/05	Applications Received Predicted Volume
13	Application to vary particulars or conditions of registration or listed registration and/or label approval if the variation is a change specified by the APVMA.	Nil	N/A
21	Application for a permit where the proposed use is a Minor Use.	\$320	506
22	Application for a permit in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an <u>emergency use</u> .	Nil	N/A

MLS

GMP Licence - applicant holds a license from an approved authority	\$150-\$300 per year*
GMP Licence -APVMA assessment required	\$250-\$1,500 per year*

HGP

Notification Number Application	\$275	30
Notification Number Renewal	\$275	170
Audit review	n/a	n/a

Other Compliance services

Consents to Import	\$0	10
TOTAL OTHER FEES		

TOTAL COST - APPLICATIONS, SERVICES AND OTHER FEES

Parliamentary Appropriation	n/a	n/a
Interest	n/a	n/a
Other Revenue	n/a	n/a
Annual Fee	\$390	7800
Reconstitution of Reserve	n/a	n/a
Levy Revenue - Balancing Factor	n/a	n/a

TOTAL REVENUE

Predicted Revenue	Levy Revenue Required	Total Revenue
\$114,600	\$171,900	\$286,500
\$5,920	\$8,880	\$14,800
\$34,465	\$51,698	\$86,163
\$0	\$0	\$0
\$61,200	\$91,800	\$153,000
\$8,190	\$12,285	\$20,475
\$7,490	\$11,235	\$18,725
Nil	\$0	\$0
Nil	\$0	\$0
Nil	\$0	\$0
\$119,475	\$179,213	\$298,688
\$429,070	\$643,605	\$1,072,675
\$95,485	\$143,228	\$238,713
\$0	\$0	\$0
\$68,045	\$102,068	\$170,113
\$3,608,750	\$5,326,185	\$8,934,935

Predicted Revenue	Levy Revenue Required	Total Revenue
Nil	Nil	Nil
\$162,000	\$1,377,178	\$1,539,178
Nil	Nil	Nil

\$119,160	\$614,081	\$733,241
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\$8,250	\$20,625	\$28,875
\$46,750	\$116,875	\$163,625
n/a	\$326,640	\$326,640

\$0	\$6,300	\$6,300
\$336,160	\$2,461,699	\$2,797,859

\$5,386,020 \$7,787,884 \$13,173,904

\$120,000	\$0	\$120,000
\$750,000	\$0	\$750,000
\$30,000	\$0	\$30,000
\$3,042,000	\$0	\$3,042,000
n/a	\$1,000,000	\$1,000,000
n/a	\$6,149,883	\$6,149,883

\$9,328,020 \$14,937,766 \$24,265,786

Actual Cost ¹
\$286,500
\$14,800
\$86,163
\$0
\$153,000
\$20,475
\$18,725
\$0
\$0
\$0
\$298,688
\$1,072,675
\$238,713
\$0
\$170,113
\$8,934,935

Actual Cost ¹
Nil
\$1,539,178
Nil

\$733,241

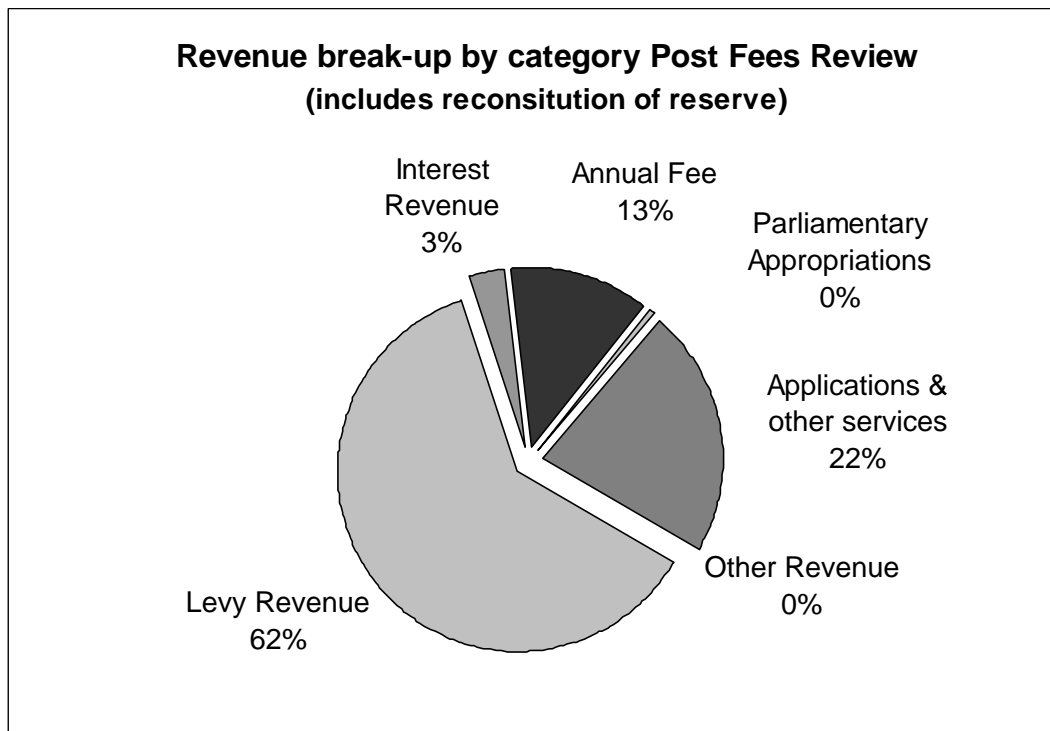
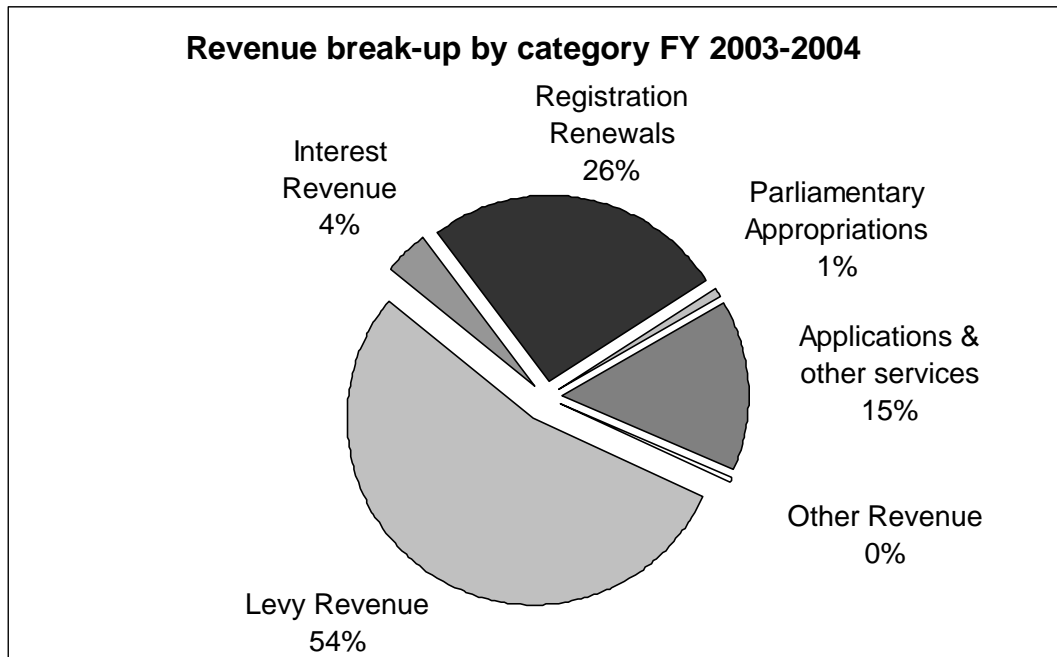
\$28,875
\$163,625
\$326,640

\$6,300
\$2,797,859

\$13,173,904

Appendix 6: ESTIMATED REVENUE BREAK-UP BY SOURCE

A comparison of the break-up of existing revenue streams (under the current system) and predicted revenue streams post fees review implementation is shown diagrammatically below.



Appendix 7: LIST OF SUBMISSIONS

- Ms Helen Arthur, Regulatory and Public Affairs Manager, Monsanto Australia Ltd
- Mr Michael Catchpole, Chief Executive, Plastics and Chemicals Industries Assoc
- Ms Janine Clark, Pest Management Officer, Growcom
- Mr Wayne Cornish, Chair - Farm Chemicals Sub-Committee, National Farmers' Federation
- Mr Peter Drummond, General Manager, Waterco Ltd - Chemical Division
- Dr Elizabeth Evans, Regulatory Affairs Manager, Bioproperties Pty Ltd
- Mr Brian Ford, Regulatory Affairs Manager, Jurox Pty Ltd
- Mr Claude Gauchat, Executive Director, Avcare Ltd
- Ms Val Hilton, Industry Development Manager, Apple and Pear Australia Ltd
- Mr Eaun Laird, Chief Executive Officer, AUSVEG Ltd
- Mr Brian Mabin, Managing Director, Mabon's Timber Protection (Aust) Pty Ltd
- Mr Geoff MacAlpine, Director, Science and Policy, Australian Consumer and Specialty Products Assoc
- Mr Douglas Rathbone, Managing Director, Nufarm Ltd
- Mr Stephen Ryan, General Manager, Australian Cane Farmers Assoc
- Mr Neil Sammons, President, The Veterinary Manufacturers and Distributors Association Inc
- Mr Alan Zappala, President, Rambutan and Tropical Exotic Growers Assoc