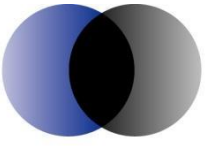
APVMA CRIS review

An independent review of the APVMA and its cost recovery policies

November 2008



ACIL Tasman

Economics Policy Strategy

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Executive summary

This report has been prepared for the Animal Health Alliance and CropLife Australia by ACIL Tasman as an independent review of the APVMA and its cost recovery policy. The terms of reference for this report are somewhat wider than those that would typically be required solely for a CRIS submission. It was considered that going back to basics to assess the role and purpose of the APVMA would inform and put context around the need for and the impact of APVMA's cost recovery policy.

In undertaking this review ACIL Tasman has found that the cost recovery approach employed by the APVMA is based on a complex set of objectives that direct it to intervene in the agricultural and veterinary (AgVet) chemicals market to protect the public's interests in the use of these chemicals, and to support the domestic industries.

This analysis has identified serious flaws in the market failure justification for the APVMA intervention in the AgVet chemicals market in Australia. This has led to the imposition of an inefficient cost recovery process.

The main findings are that:

- There are no clear systemic market failures in the use of AgVet chemicals in Australia that justify the use of an uncapped levy based on the sales value of registered products designed to promote the domestic AgVet chemical industry.
- A sales based levy subsidises chemicals of low market value by taxing those of high market value, which:
  - creates disincentives for R&D in an industry where R&D is the key source of future growth
  - creates perverse incentives for products to be registered that may have little or no value to the Australian community. This increases the costs of regulation and delays the registration of higher value chemicals
  - increases the input costs of Australian farmers (who have limited capacity to pass these costs on) and reduces the range of chemicals offered than would otherwise be the case.
- The current cost recovery system is not aligned to the externality risk of registered veterinary medicines and agricultural chemicals and therefore does not create any incentives for them to be better managed by the supplying companies or consumers.
- There does not appear to be a strong economic case for the APVMA to include compulsory efficacy in the registration of new active ingredients and formulations.

  - However, where consumers do not have access to reliable and inexpensive product information (particularly where animal welfare is an issue), or where the costs of product failure exceed the costs of regulation, there may be a justification for efficacy to be included in the registration process
  - The APVMA's role in efficacy testing should be subject to close scrutiny, including a full cost benefit analysis in any review of the legislation in future.
- A 100 per cent cost recovery policy (which under current arrangements can actually exceed 100 per cent) does not appear to be justified given that the APVMA undertakes a number of ministerial and public good tasks, many of which are prescribed in the *Agricultural and Veterinary Chemicals Code Act 1994 (the AgVet Code)* and the *Agricultural and Veterinary Chemicals Act 1994*.
- An uncapped levy system does not create incentives for the APVMA to be responsive to the industry's needs or to become more efficient in its delivery of regulatory, ministerial and public good services.
- Chemical companies and consumers face strong incentives to meet international trade standards, and to ensure their products do not unduly affect the capacity of other exporters to meet voluntary export contract specifications. The role of the APVMA in *furthering of trade and commerce between Australia and places outside Australia* needs to be more clearly defined to ensure that the role of the APVMA is confined to the management of trade related externalities only.

The inefficiencies identified in this report are ultimately borne by users of the agricultural and veterinary chemicals. As many of these users operate in markets which offer negligible opportunities for price discrimination the ultimate outcome is less competitive Australian agricultural industries.

Also an inappropriate and inefficient cost recovery system posts the wrong incentives for the AgVet chemical industry and for the APVMA to better manage the unintended effects on the use of veterinary medicines and agricultural chemicals in Australia.

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Figures and tables

List of acronyms

ACCC	Australian Competition and Consumer Commission
AgVet	Agricultural and veterinary
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
COAG	Council of Australian Governments
CRIS	Cost recovery impact statement
DAFF	Department of Agriculture, Fisheries and Forestry
DFAT	Department of Foreign Affairs and Trade
GM	Genetic modification
GMOs	Genetically modified organisms
MINCOS	Ministerial councils
MNE	Multi National Enterprise
MORAG	Manual of requirements and guidelines
MRL	Maximum Residue Limits
NAFTA	North American Free Trade Area
NICNAS	National industrial chemical notification and assessment scheme
OGTR	Office of the Gene Technology Regulator
PC	Productivity Commission
PIMC	Primary Industries Ministerial Council
R&D	Research and Development
TGA	Therapeutic Goods Administration
TPA	Trade Practices Act
WEA	Wheat Export Authority

1 Introduction

ACIL Tasman has been commissioned by Animal Health Alliance (The Alliance) and CropLife Australia to conduct an independent review of the Australian Pesticides and Veterinary Medicines Authority (APVMA) and its cost recovery policies.

The terms of reference of this report are somewhat wider than those that would typically be required solely for a CRIS submission. The reason for this is that the cost recovery approach employed by the APVMA appears to have been designed to meet a complex set of objectives established in the legislation that creates the APVMA and gives it its powers. Therefore an analysis of the cost recovery policies of the APVMA requires a wider assessment of the nature and appropriateness of this government intervention in the Australian AgVet chemicals industry.

This report analyses:

- the agricultural chemical and veterinary medicine innovation system and markets in Australia (see chapter 2 and chapter 5);
- the current registration and levy structure used by APVMA. It compares this structure with approaches used by three other Australian regulatory bodies (see chapter 7);
- the appropriateness and effectiveness of the APVMA in meeting the objectives of the Act. It considers how relevant the objectives are in the current agricultural chemical and veterinary medicines innovation system and market.

2 Nature of the task

This report is broadly divided between analysing the appropriateness and effectiveness of the enabling legislation, and the efficiency by which the APVMA discharges its obligations under the relevant Acts.

As with any government intervention, if the basis of the intervention embodied in the relevant Acts and the interpretation of them are based on weak externality arguments, then activities of the agency charged with meeting the objectives of the Act may lead to intervention failures, inefficiencies or both.

2.1 Appropriateness and effectiveness

Animal Health Alliance and CropLife Australia members are concerned about the method by which the APVMA recovers the costs of registering and overseeing the agricultural and veterinary chemicals registration process in

Australia. The main concerns relate to what they believe are poor alignment of costs and services leading to significant cross subsidisation between products, companies and markets.

At first glance the cross subsidies appear to stem in part from the *Agricultural and Veterinary Chemicals Code Act 1994 (the AgVet Code)* and the APVMA's interpretation of certain aspects of the the *AgVet Code*. In particular clause (c) in the objectives of the code may be interpreted as giving direction to APVMA to ensure that the scheme promotes domestic AgVet chemical production:

> that the furthering of trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well being of the economy and require a system for regulating such products that is cost effective, efficient, predictable, adaptive and responsive (clause (c) of the *AgVet Code 1994*)

One of the key objectives of this analysis is to determine whether an intervention that promotes the domestic industry is justified. This type of intervention would be justified on the grounds that the market, if left to its own devices, would systematically under-invest in the domestic AgVet chemicals industry.

To establish whether this intervention is justified, an analysis of the Australian agricultural chemical and veterinary medicines innovation system and market has been undertaken to determine whether there are any systemic market failures leading to under-investment by Australian or international interests.

Addressing trade[1] and investment market failures through the registration and levy system is a separate issue from the registration and monitoring of new agricultural chemicals and animal medicines in Australian agriculture. The primary aim of the registration and usage system should be to manage the externalities of the application of these chemicals (externalities are unintended and unpriced effects of the products. For example effects on human health and the environment are two of a number of market failures identified by economists). As a general rule cost recovery should be aligned with the management of potential externalities. That is, those that cause the externalities should meet the costs of managing them.

Thus this analysis has considered the effectiveness of APVMA by reviewing how well the registration and levy system aligns to the risk of externalities from

[1] The APVMA's protection of trade specifically relates to the setting of residue detection standards and limits so that export shipments do not exceed importing countries' residue standards.

the use of agricultural chemicals and veterinary medicines and whether they are being reduced as a result of the system currently in place.

There is also potential that structuring a registration and levy system to address trade and investment market failures (real or perceived) may conflict with the management of externalities of agricultural chemical and veterinary medicine use.

2.2 Efficiency

The second area of analysis for this project has been to look at the efficiency of the APVMA registration and levy system. This part of the project analyses:

- How well the charges for services align with the cost of providing them?
- Are the registration fees and levies aligned with the beneficiaries of the services (e.g. what are the public good functions of the APVMA)?
- Whether the costs of the services provided seem reasonable. That is are the costs of running APVMA consistent with the costs of similar services provided by other authorities?
- Is the APVMA responsive to industry requirements and does it provide appropriate services in a timely manner?

3 APVMA registered products

The APVMA's regulation of agricultural and veterinary chemicals touches directly or indirectly on chemical importers, manufacturers, packagers, wholesalers and retailers. Product coverage includes large and small animal (including companion animal) veterinary medicines, pesticides, and other agricultural chemical products, as well as chemicals used domestically in gardens, pools and spas plus chemicals used in timber preservatives and marine anti-fouling paints.

There is very limited information on the number of participants in the sectors covered by the APVMA's regulatory processes. However, the 2005 CRIS suggests that the majority of products actually registered under the APVMA system are either not sold in the market place or have relatively limited sales. For example the CRIS reported that 801 companies renewed a total of 7,629 product registrations with the APVMA in 2003-04. Some 748 of these companies had total agricultural and/or veterinary product sales turnover of less than $5,000.

More than a quarter of the registered products had no sales revenue; another 14 per cent had annual sales revenue of $10,000 or less; with another 10 per

cent having sales revenue between $10,001 and $25,000. Only 29 per cent of all products registered had annual turnover of more than $100,000.

Table 1 **APVMA registered products and sales by sales thresholds (calendar year 2002)**

Product Sales Thresholds	No. of	%	Sales	Sales
$	Products		$	%
0	2202	29%	0	0%
1 - 10,000	1098	14%	4,871,456	0%
10,001 - 25,000	756	10%	12,736,919	1%
25,001 - 100,000	1389	18%	77,939,864	4%
100,001 - 250,000	851	11%	136,383,716	7%
250,001 – 1,000,000	940	12%	474,604,941	26%
1,000,001 - 5,000,000	345	5%	679,304,935	37%
Greater than 5,000,000	48	1%	466,941,535	25%
Total	7629	100%	1,852,783,366	100%

Data source: DAFF 2005, Table 2.

What would be surprising to an independent observer is the predominance of registered products with minimal or even no sales revenue. The 2005 CRIS states that the reason behind the dominance of low sales for its registered products is the nature of the Australian market:

> Australia is a small market in global terms, sales of most products are relatively low (DAFF 2005, p.7).

However sales of zero or less than $25,000 per annum for a registered product are incredibly low even in the context of the Australian market. An independent observer who is not aware of the APVMA's cost recovery process may concur with this view. However, once the nature of the regulation cost recovery process is understood it becomes clear that this process could be encouraging the registration of products with little if any prospects for sales. Indeed the 2005 CRIS states:

> 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 [cost recovery] model (p.7).

As will be discussed in more detail later in this report, the cost recovery approach used by the APVMA creates perverse incentives for products to be registered that may have little or no value to the Australian community.

There are a number of reasons why there are a large number of products with little or no sales volumes:

- Some products are registered by companies who have no intention of selling the product but ‗sub lease' to other companies who may wish to (speculative registrations)
- Some products may no longer be sold due to a range of factors but the registration is maintained to allow the product to be reintroduced at short notice if demand increases (this may be due to changes in seasonal conditions or the infrequent presence of the target pests and diseases) regardless of the age of the registration
- Some companies may register one or more formulations of the same product at the same time even when only one formulation is anticipated to be sold (scope economies)
- Some products do not meet the sales expectations of the registrant.

Most of these types of registrations are the result of cross subsidies inherent in the fee structure, and no requirement to reregister chemicals based on longevity in the market, current science or changed industry circumstances.

Thus it is highly possible that the approaches used for APVMA cost recovery and not the nature of the innovation system or the market for agricultural and veterinary chemicals has resulted in the composition of products registered.

These perverse incentives can result in:

- a waste of regulators time:
  - and as a consequence a slower than optimal registration timeframe for products that, when brought to the market, will have high value to the community (demonstrated through sales revenue achieved)
- higher than necessary costs for companies making agricultural and veterinary chemicals, which are subsidising the registration of products that are simply ―sitting on the shelf‖
  - and as a consequence higher costs for agricultural and veterinary chemical users
    - … which can in turn reduce the competitiveness of Australian agriculture.
- Lastly, subsidies in general lead to a misallocation of resources to areas that would not survive in the absence of policy intervention. In other words, the capital and labour employed in the subsidised industry or firm could have been used more efficiently in others.

Some may argue that these perverse outcomes may be excused because the Australian market is too small for large companies to justify substantial investment in R&D here. Therefore protection for smaller Australian companies can be justified (APVMA, 2005). Most economists, on the other

hand, would argue otherwise. Firstly, it is important to note that in a globalised world countries will have access to the findings and potential applications of research and development, regardless of whether a particular country undertakes the R&D itself. This is provided the recipient country has the capacity to adapt the innovation to its own circumstances.

This is more so for industries where the major players are large global corporations that undertake a substantial amount of R&D across the world. Secondly, economists argue that a system of cross-subsidisation leads to major inefficiencies by, for example, increasing costs faced by consumers. We treat these issues below.

3.1 Innovation in Australian agricultural and veterinary chemicals

3.1.1 Background

As a broad rule, the active ingredients of most chemicals are based on the physiology of plants and animals, and therefore the efficacy of the active ingredient is likely to be similar for the target species wherever it is found. This is based on the notion that the physiology of plant and animal species is generally consistent around the world. However, the degree of adaptation of AgVet innovations, particularly new active ingredients varies across and within industries in Australia. For example agricultural chemicals commonly have higher levels of efficacy on weeds in Australia than they would for the same weed in another country. They may also have higher levels of residues.

Similarly the method of application of the active ingredient is not universal as there are considerable differences between the production systems and situation of the target species. For example, some herbicides are applied to plants around the world. But the formulation (concentration, mixtures with other active ingredients, etc.) of the products containing a particular chemical differ widely across the many markets where it is sold. Similarly the packaging also differs widely to cater for the wide range of production systems and situations it is used in.

This has important implications for the AgVet chemical innovation system. The wide application of active ingredients tends to lead to consolidation of the active ingredient research (with some exceptions), while formulation and packaging development could be more dispersed and located in or near the final markets for the products.

Another significant change in the AgVet chemicals industry that has altered where and by whom AgVet chemical R&D is undertaken, has been the wider commercialisation of GM technology and biotechnology. The first wave of

GMOs to be adopted has consisted of plants that have a resistance to particular herbicides or are resistant to certain pests. In many instances this has tied a group of herbicides to specialised crop production systems, and in most instances, extended the use of several active ingredients.

Where crops have a resistance to a pest this has largely replaced the use of pesticides. GM cotton for instance contributed to a dramatic decline in the use of endosulphan in Australia.

Over the last 15 years Ag R&D has been heavily focused on the development of new biotechnology techniques and applications while integrating active ingredients of crop chemicals into specialised GM crop production systems. GM development has been conducted in parallel with ongoing formulation development. Both these types of R&D require considerable scale as the costs and risks are high. This adds further pressure to consolidation in the Ag industry, particularly when most of the new technology is protected by patents and licensing agreements.

4 The pesticide industry

4.1 Background

In Australia, and around the world, the major market for pesticides is the agricultural sector, which is thought to account for roughly 80 per cent of pesticide consumption. Also known as crop protection products, pesticides are used to protect plants and crops from the damage caused by weeds, insects and disease. They are applied at various stages of the production process: in the seeding stage, to harvested produce or during processing, and/or during packaging and transportation. The vast majority of pesticides are consumed by wheat and other crop producers, including those involved in cereal grains, coarse grains, pulses, and oilseeds (IBISWorld, 2008).[2]

Common forms of pesticides are as follows:

- Herbicides, which are used to prevent or reduce weeds and thereby reduce the need for manual and/or mechanical weeding. By reducing the need for cultivation, herbicides are often used in conservation farming and minimum cultivation techniques.

[2] Much of the data employed in this study comes from IBISWorld (2008). It must be noted that there may be some imperfections with these data as it is based on a variety of surveys, which often lead to substantial measurement error. However, as long as these errors remained unbiased— that is, all companies have the same probability of being over or under represented— then our figures should remain reliable. Additionally, this data source is the most comprehensive one available and we have no choice but to rely on it.

- Fungicides, which are used to fight fungal plant diseases thereby improving crop yields and quality and;
- Insecticides, which are used to control damaging pests.

According to IBISWorld (2008), within Australia herbicides are the largest product segment in pesticide manufacturing, accounting for roughly 55 per cent of sales. This is followed by insecticides (20 per cent) and fungicides (10 per cent). Other products such as plant growth regulators, soil fumigants, rat poison and various other agricultural and pastoral chemicals account for the remainder. Note that these proportions will vary on a year to year basis in line with changes in weather conditions, crop areas, and disease/pest outbreaks.

4.2 Size of the industry and major players

4.2.1 The pesticide industry at a glance

The pesticide manufacturing industry represents approximately 0.2 per cent of total manufacturing in Australia (IBISWorld, 2008). The size of the industry has been adversely affected by the fall out effects associated with the onset of drought in 2002-03. This has seen the industry contract in size with revenue levels (in real terms) halving between 1999-2000 and 2004-05 (IBISWorld, 2008).

Table 2 corroborates this by indicating a negative trend in key indicators such as industry revenue, employment and domestic demand for pesticides from 2002 to 2007. In fact, the only variable exhibiting an upward trend is industry gross output. This trend no doubt reflects a global rise in the price of pesticides resulting from increased demand for foodstuffs during this period[3].

Table 2 **Key characteristics of the Australian Pesticide manufacturing industry, 2002-2007 ($m)**

	2002-2003	2003-2004	2004-2005	2005-2006	2006-2007
	$m	$m	$m	$m	$m
Domestic industry revenue	941	824	892	875	800
Domestic industry gross product	183	195	212	224	230
Employment [a]	1163	1123	1343	1330	1255
Exports	136	106	98	96	76
Imports	350	351	381	346	347
Total Wages	87	86	84	91	85
Domestic Demand	1155	1069	1176	1125	1071

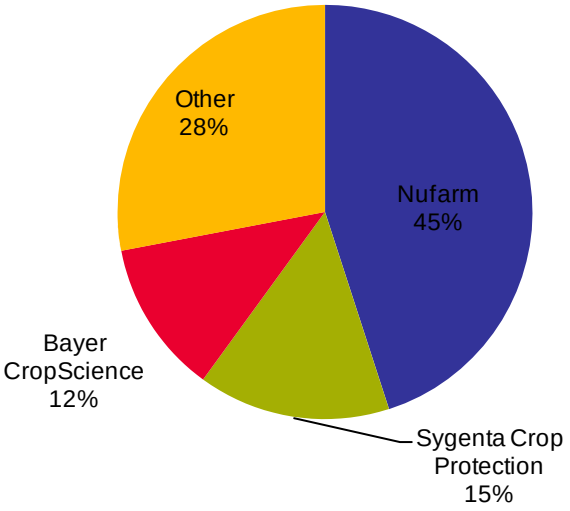
[3] Increasing demand for grains and other foodstuffs from emerging economies (mainly in Asia) and North and South America is causing upward pressure on the global price of pesticides (see Nufarm Ltd, 2007 and Bayer CropScience, 2008).

a Employment is measured in labour units.
Data source: IBISWorld (2008).

4.2.2 Major players

The major pesticide manufacturers in Australia and their respective market share (in 2007) are summarised in Figure 1. The figure shows that Nufarm Ltd was the largest pesticide manufacturer in the country in 2007, with a total market share of 45 per cent. In second place was Syngenta Crop Protection Pty Ltd, which in 2007 had a market share of 15 per cent. The third largest pesticide manufacturer in Australia is Bayer CropScience, which in 2007 had a market share of 12 per cent. Amongst those firms classified as _other' in Figure 1, the largest is Dupont Australia Ltd, which in 2006 to 2007 had a market share of approximately 3 to 5 per cent.

Figure 1 **Major pesticide manufacturers in Australia and their market share, 2007**



Note: The data presented in the figure are upper bound estimates. The lower bound estimates are on average two percentage points below the presented figures.
Data source: IBISWorld (2008).

Nufarm is the only one of these major players that is an Australian based multinational enterprise (MNE). The agricultural and chemical operations of Nufarm are based primarily around crop protection products.

Nufarm operates within the _non-patented proprietary' or generic segment of the crop protection industry. This means that its products are not covered by patent protection, which implies that the company does not undertake a substantial amount of original R&D (IBISWorld, 2008). Nufarm's R&D expenditure in 2007 totalled US$30 million (Nufarm Ltd, 2007). Although this is a large figure when taking into account that Nufarm is a relatively small company, their R&D expenditure is small when compared to the

approximately US$400 million spent by Syngenta in that year (IBISWorld, 2008). R&D in this industry is treated in more detail in the following section (section 4.3).

The remaining three major players mentioned above are all subsidiaries of major MNEs based in the United States or Europe. Bayer CropScience and Syngenta, for instance, are the largest players in the global crop protection industry. Aside from crop protection, Syngenta has also specialised in seeds and in crop biotechnology. Bayer CropScience has an even more diversified portfolio. Apart from crop protection, this firm is also a leading player in biotechnology, seeds market, the turf and ornamental markets, professional pest management markets, and consumer lawn and garden markets.

Syngenta's primary markets are Europe, Africa, and the Middle East, although its activities in the NAFTA region have been increasing. Similarly, Bayer CropScience is relatively larger overseas. The bulk of this firm's business activities are carried out in Europe, the Americas, and Africa. This is also the case for DuPont, which operates mainly in Europe and the NAFTA region.

Nufarm, Syngenta, Bayer CropScience, and Dupont Australia undertake substantial investments in R&D. This is not surprising as the base of industry competition for these companies lies with product performance and product innovation, as well as the growing number of new innovative release techniques being developed (IBISWorld, 2008). The following section (section 4.3) takes a careful look at R&D in the pesticides industry and relies on information from the major industry players to shed light on the extent of R&D being undertaken in Australia.

4.3 Research and Development intensity

4.3.1 R&D in pesticide manufacturing: A global perspective

The global pesticide manufacturing industry is research intensive in nature. According to a recent report on R&D expenditure in the global agrochemical industry, the ten largest companies spent approximately $2.3 billion on R&D in 2004 alone (Phillips McDougal, 2005)[4]. The same report explains that in addition to the studies associated with new product discovery, the agrochemical industry undertakes a significant amount of R&D aimed at maintaining and developing the existing product portfolio. Some of these studies will be undertaken to extend the application and use of existing

[4] Globally, the ten largest companies in 2005 were: BASF, Bayer CropScience, Dow AgroScience, DuPont, FMC, Monsanto, Makhteshim Agan, Nufarm, Sumitomo Chemical, and Syngenta.

products to other crop pest situations or to other country markets. Increasingly, a number of studies are also being undertaken to satisfy the registration requirements of regulatory bodies such as the US Environmental Protection Agency or the APVMA. Table 3 summarises this information.

Table 3 **The global agrochemical industry R&D expenditure by R&D Phase (ten largest firms), 2004 USD**

R&D Activity	Expenditure	% of Total
	US $'m	
Discovery	705.2	31%
New product development	506.8	23%
Cost of managing existing business excluding re-registration	558.7	25%
Re-registration	397.2	18%
Patents	82.1	4%
Total	2250	100%

Data source: Phillips McDougal (2005).

4.3.2 R&D in pesticide manufacturing: An Australian perspective

Although the global pesticides manufacturing industry is research-intensive, the proportion of R&D undertaken in Australia by the major market players seems small. However, there is insufficient public information available to assess the actual monetary value of their contributions to R&D in Australia.

In Australia, pesticides manufacturing is mostly by formulation, with manufacturers basically involved in the production of developed end-products for the domestic market. These products, which are formulated from imported active ingredients, are designed to suit local characteristics and to comply with specific registration requirements. In other words, the R&D intensity of Australian pesticide manufacturers is marginal compared to their US and Europe based counterparts (IBISWorld, 2008).

The extent of local R&D depends, in large part, on environmental and policy-related factors that lead to the need for significant variability in the imported products. As indicated in IBISWorld (2008, p.23):

> While research and development activities tended to be limited to a few countries, chemical synthesis and product formulation occurs in numerous locations, often reflecting the existence of import tariffs on finished products, freight saving advantages, the regulatory environment or the need to adapt the product to the local market.

R&D in Australia by the major market players

ACIL Tasman understands that Nufarm, Australia's largest AgVet company, does not undertake a substantial amount of R&D in Australia. It seems that

this choice is driven by the company specialising in an optimal sales strategy. It is understood that the majority of Nufarm's R&D is undertaken in other countries.

Syngenta Crop Protection, the second largest firm in Australia, is one of the biggest spenders on R&D in the world. According to IBISWorld (2008), the firm dedicated a total of US$490 million to R&D in crop protection activities in 2006. Note, however, that both its manufacturing and R&D activities are predominantly based in Switzerland, the UK, and the US.

Within Australia, Syngenta is involved in a number of relatively small collaborative R&D projects with co-operative research centres. Some major research organisations currently involved with Syngenta are: the CSIRO; Daratech; the Universities of Melbourne and Sydney; the Forest Herbicide Management Research Group; and the Australian Department of Agriculture, Fisheries and Forestry (IBISWorld, 2008).

Additionally, Syngenta has recently established a new research partnership with Queensland University of Technology to develop enzyme systems for converting sugar cane waste into biofuel. The partnership complements a new ten-year agreement signed with Verenium Corporation to develop enzymes for converting pre-treated cellulosic biomass (Syngenta Global, 2008). This highlights Syngenta diversification into other areas of agribusiness.

Bayer CropScience, the third largest firm in Australia, is the world's biggest R&D spender in the agrochemical industry (IBISWorld, 2008). Bayer's 2007 annual report cites that the company spend approximately €637million (USD455 million) (Bayer, 2008). The focus of its R&D activities is not only on launching new products, but also on increasing the efficiency of existing compounds and extending product life cycles. Since 2000, it has introduced 16 new substances. Moreover, Bayer CropScience is likely to launch an additional 10 substances between 2006 and 2011 (IBISWorld, 2008).

Within Australia, Bayer CropScience focuses a significant proportion of its R&D activities on broadacre, horticulture, cotton and seed treatments. Additionally, the firm concentrates on the blending, formulating and re-packaging aspects of R&D within Australia. However, many of these products are branded generics and their active ingredients cannot be patented. The company is also thought to have been involved in agricultural biotechnology research within Australia for the last eight years (IBISWorld, 2008).

DuPont also carries out part of its R&D activities within Australia. According to IBISWorld (2008), the firm's R&D activity in Australia focuses on materials for herbicides and fungicides. For instance, for over a decade it has operated a

joint venture with the CSIRO to develop compounds for new agricultural chemicals.

Dow AgroSciences spends about 2 per cent of its Australian turnover on R&D to support the Australian market. This level of spending supports the introduction of on average 1 new active per year, 1 to 5 new formulations and 4 to 10 new uses for existing products (personal communication with Dow AgroSciences 9-12-2008).

The actual amount of expenditure on R&D in Australia by these firms is not publicly available. What is clear is that their R&D expenditure is often undertaken in partnerships with external Australian organisations. According to Phillips McDougal (2005), the proportion of agrochemical R&D expenditure that is devoted by the average firm to work undertaken by external bodies is approximately 16 per cent. Note however, that the actual amount spent in Australia should be well below this as this country remains relatively less research intensive than other OECD nations (OECD, 2006).

Implications of R&D expenditure in Australia and the World

In this section we noted that although the Ag chemicals industry is particularly R&D-intensive, the expenditure on R&D by the major players in Australia is dwarfed by the amount of expenditure undertaken by these same companies in the United States and Europe. As a result, some may argue that protection for smaller Australian industries can be justified to ensure that this country undertakes R&D.

However, much of the overseas expenditure is directed at the development of new active molecules while domestic expenditure is largely dedicated to adapting the overseas innovations for Australian conditions. This investment is in the form of new formulations, applications and to a lesser extent packaging.

As discussed above, this cannot be justified on economic grounds. There is no reason why a particular country must undertake investment in R&D when similar outcomes may be obtained by importing knowledge and findings from other nations (free riding on the innovations produced elsewhere). Although importing goods, services and knowledge is often perceived as a transfer of wealth from the importing to the exporting nation, economists have shown that there are substantial gains to be made from that trade, even for importing nations. The primary argument put forth is that by importing goods and services from other nations, rather than producing these ourselves, economies are able to free up resources and employ them in sectors where the country has a comparative advantage.

5 The animal health industry

5.1 Background

The information provided in this section comes from Business Decisions (2007) [BD henceforth], unless otherwise specified. BD is a comprehensive study of the Australian animal health industry. The analysis relies on surveys involving approximately 80 per cent of the industry. The study and the surveys focus on the role of domestic and international R&D and industry regulation in maintaining the competitiveness of the industry. Some discussion is also provided on the widespread benefits this industry generates to the wider Australian community by ensuring that the rural sector remains internationally competitive.

Animal health companies supply Australian farmers and pet owners with a large range of pharmaceuticals, vaccines, insecticides, acaricides and diagnostics developed and produced using complex chemical, pharmacological, and biological technologies. These products are critical inputs for farmers, playing a major role in determining efficiency and maintaining Australia's status as one of the world's leading exporters of meat, livestock, and fibre. However, despite its global importance, the Australian animal health sector remains relatively small.

5.2 Size of the industry and major players

According to survey information, annual sales of animal health products in Australia in 2006 were around $630 million. This represents approximately 3 per cent of global sales, excluding nutritional feed additives. The scale of demand is, however, highly volatile because of the influence of climate (most notably drought) and of global trade patterns.

The Australian market for animal health products is small and structurally fragmented. This reflects the need to provide different products for a wide range of diseases affecting each of a large number of species. This has led to a large number of products with low annual sales.

BD does not provide information on who the major market players are in this industry. However, according to research conducted by ACIL Tasman we can conclude that some of the largest firms in this industry are Bayer Australia Ltd (Animal Health), Boehringer Ingelheim Pty Limited, Elanco Animal Health, Fort Dodge Australia Limited, Intervet Schering-Plough Pty Ltd, Merial Australia Pty Ltd, Novartis Animal Health Australasia Pty Ltd, Pfizer Animal Health, and Virbac (Australia) Pty Limited. All of these companies are subsidiaries of global multi-national corporations.

5.3 Research and Development intensity

According to survey information, innovation is the principal long-term driver of competitiveness in the Australian animal health industry. Due to the cost, time, and risk associated with the development of new animal health products, most R&D investments are now made initially in global research centres in the EU and the US by a small group of around 10 multi-national companies[5]. Once this global development process is complete, core test data is made available to subsidiary companies throughout the world in the form of intellectual property. National managers then decide whether to launch the new product, taking into account intellectual property and reputation issues, market value, local operating costs (selling, marketing, technical support, and manufacturing), and regulatory requirements.

Innovation in Australia occurs principally through the importation of intellectual property developed in these global research centres. Animal health companies invest approximately $50 million in R&D in Australia each year. Of this, it is estimated that approximately 80 to 85 per cent of current innovatory activity is based on bringing into Australia core test data generated elsewhere in the world. The aim of this R&D investment is to meet additional test and risk assessment requirements needed to gain Australian market access for global products. Australian-specific requirements include efficacy, anti-microbial issues, user safety, trade, and residue tests; field trial permits; and importation permits (involving AQIS, as well as APVMA).

Defensive R&D, the practice of undertaking R&D for the purpose of maintaining product registrations to comply with regulation from regulatory bodies, absorbs at least 25 to 30 per cent of Animal health companies' total R&D budgets in Australia. Defensive R&D refers to mandatory expenditure needed to keep existing products on the market. According to the firms surveyed by BD, this practice diverts scarce resources away from innovation and triggers reductions in the availability of products.

R&D expenditure in Australia is predominantly undertaken by the subsidiaries of global, multi-national animal health companies. However, a significant proportion (around 50 per cent) of this R&D expenditure is outsourced to specialist Australian contract research companies, universities, and research institutes. According to BD the quality of the science base in these contract

[5] Bayer Group, for instance, undertakes its R&D and manufacturing activities mainly in Monheim, Germany, and Shawnee, Kansas, United States (Bayer, 2007).

research organisations is a major factor maintaining Australia's attractiveness for some aspects of global R&D investment[6].

5.3.1 Type of R&D being undertaken

Importation of global intellectual property is greatest for major new products for livestock or companion animals; for products based on advanced technologies; and for pharmaceuticals. Moreover, local R&D is higher for vaccines and for products that target minor species in a global context, especially sheep.

Globally, R&D in animal health is for the most part geared towards companion animals (including horses). Major areas of investment are on anti-infective and parasiticide products, as well as active ingredients for the treatment of non-infectious disorders such as renal failure, pain, cancer and congestive heart failure (see Bayer, 2007 and Merial, 2008)[7].

Note however, that other major companies such as Elanco and Merial Australia seem to be becoming increasingly specialised in pharmaceuticals for production animals. Elanco is a major manufacturer of pharmaceutical products for the global dairy, beef, feedlot, swine, poultry and veterinary industries, while Merial Australia is the market leader in pharmaceuticals for sheep, cattle, swine, and horses.

6 APVMA: Role and purpose

The Australian states and territories have constitutional power over the manufacture, supply, and use of agricultural and veterinary chemicals. In 1991 an Australian National Registration Scheme for the management of pesticides and veterinary medicines was established in a partnership between the Australian states and territories and the Commonwealth Government. In 1992 the APVMA (then called the National Registration Authority) was established and commenced the scheme's administration in 1993.

According to the APVMA there are now over 7,000 different pesticide and veterinary medicine products available in Australia. The APVMA argues that given the wide range of goods available, there is an important role for

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6 For example, Elanco, the animal health division of Eli Lilly, manufactures a range of animal health premixes, and is the sole global supplier of the Rumensin Anti-Bloat Capsule, an innovative product researched and developed in Australia in collaboration with the CSIRO (Lilly Australia, 2008).

7 In 2007 Bayer alone had a total R&D expenditure budget of around €2.8 billion (the total for all of its business divisions)—by far the largest R&D budget of any German company with investments in the animal health sector (Bayer, 2007).

government in ensuring that products entering the domestic market pose no unacceptable risk to human health, worker safety, the environment, that the products work effectively, and that they are not unduly prejudicial to international trade. Additionally, the APVMA aims to ensure that products are suitably formulated and properly labelled (APVMA, 2004).

6.1 Legislative objectives

The APVMA's governing legislation is the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and *Agricultural and Veterinary Chemicals Code Act 1994*. As its name implies, the Agricultural and Veterinary Chemicals (Administration) Act's objective is to create a body with the authority to administer laws relating to the agricultural and veterinary chemicals on behalf of Australian Governments. Part 1, Section 3 of the Act states:

> The object of this Act is to establish a national registration authority to administer such laws of the Commonwealth or of the States and Territories relating to agricultural and veterinary chemical products as confer functions and powers on the Authority.

Part 1, Section 1 of the *Agricultural and Veterinary Chemicals Code Act* states that the Code's objectives are in relation to existing and new constituents for use in Agricultural and Veterinary Chemicals products as well as the manufacture and supply of the same products:

> The object of this Code is to make provision for and in relation to:
>
> (a) the evaluation, approval, and control of the supply, of active constituents for proposed or existing agricultural chemical products or veterinary chemical products; and
>
> (b) the evaluation, registration, and control of the manufacture and supply, of agricultural chemical products and veterinary chemical products.

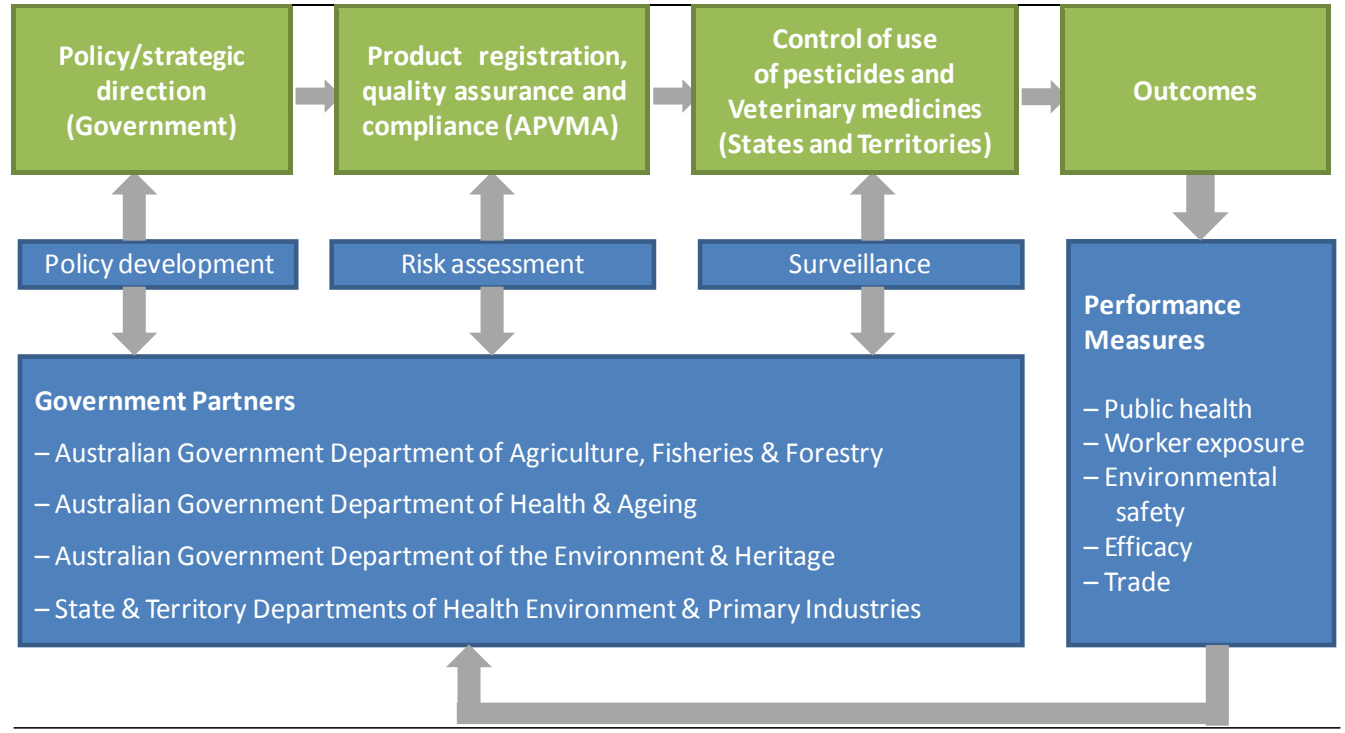
The APVMA in undertaking its activities does not establish policy, rather the APVMA implements policy, which has been established by the Primary Industry Ministerial Council (PIMC) under the advice of the Council's Product Safety and Integrity Committee.

PIMC consists of the Australian, State and Territory Governments (COAG), as well as the New Zealand government ministers responsible for agriculture, food, fibre, forestry, fisheries and aquaculture industries/production and rural adjustment policy. The Council is the peak government forum for consultation, coordination and, where appropriate, integration of action by governments on primary industry issues (MINCOS, 2008).

The APVMA has described the regulatory framework with reference to Figure 2, which highlights that the framework involves a number of Government

partners, who have responsibility for developing and implementing strategic policy. The APVMA undertakes risk assessment and registration on behalf of these government agencies. However, the APVMA is not responsible for regulating use after retail sale; this responsibility remains with the state and territory governments. Of particular interest in the figure are the outcomes and performance measures, which include efficacy. As will be discussed later, it is not clear whether efficacy should be an outcome relevant to specific government interventions or the APVMA's activity.

Figure 2 **Regulatory framework**



Data source: Introducing the Australian Pesticides and Veterinary Medicines Authority, APVMA website accessed on the 15-09-2008..

In undertaking risk assessments prior to registration the APVMA undertakes evaluations in the following areas:

- chemistry and manufacture;
- product efficacy;
- toxicology, metabolism and kinetics;
- residues and trade;
- antimicrobial risk assessments
- occupational health and safety; and
- the environment.

Given the range of disciplines covered by the APVMA, it is not surprising that it routinely outsources many of these tasks to, amongst others, a number of

Australian and State government agencies, such as the Office of Chemical Safety, the Commonwealth Department of the Environment and Water Resources, and State and Territory departments responsible for agriculture and primary industries (APVMA, 2004).

On the whole, the primary activities of the APVMA and its partner organisations are to:

- evaluate active constituents, products, and their labels
- review existing chemicals where potential risk to safety or performance have been identified
- issue permits for emergency uses, minor uses or for research purposes
- conduct a national program of compliance and surveillance up to and including the point of retail sale
- manage a manufacturer's licencing system
- collect statistics on active ingredient importation and usage.

6.2 Is there a clear economic need for the AgVet Code and APVMA?

Governments in Australia and around the world intervene in the workings of their economies for a variety of reasons including to:

- achieve social and equity goals
- address chronic failures in the operation of markets
- comply with international agreements
- create options for future economic growth and wealth creation.

To justify the existence of a regulatory body such as the APVMA four important conditions must be met:

- there must be a clear understanding that there is a limited capacity in Australian business to ensure that their products exhibit no prejudicial effects to human health and the environment; while simultaneously seeing that their products work effectively and are not unduly prejudicial to international trade
- the benefits of the regulation need to exceed its costs
- the risk of intervention failure is not excessive and does not exceed the risk of the externality targeted
- further it is important to verify that there is no other government body that is undertaking these tasks. This is referred to as duplication.

These issues are addressed in the following discussion.

6.2.1 Is there a limited capacity in Australian business to undertake these tasks?

The long title to the *Agricultural and Veterinary Chemicals Code Act 1994* suggests that government recognised there were a number of market failures, trade and industry assistance objectives that underpin the need for the Code and the APVMA. The Act states:

> An Act to make provision for the evaluation, registration and control of agricultural and veterinary chemical products, and for related matters, for the purposes of the *Agricultural and Veterinary Chemicals Act 1994*
>
> RECOGNISING:
>
> (a) that the protection of the health and safety of human beings, animals and the environment is essential to the well-being of society and can be enhanced by putting in place a system to regulate agricultural chemical products and veterinary chemical products; and
>
> (b) that the principle of ecologically sustainable development requires a regulatory system that is designed to ensure that the use of such products at the present time will not impair the prospects of future generations; and
>
> (c) that the furthering of trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well being of the economy and require a system for regulating such products that is cost effective, efficient, predictable, adaptive and responsive; and
>
> (d) that it is desirable to establish a regulatory system that is open and accountable and gives opportunity for public input with respect to the regulation of such products;
>
> (e) that the system should, so far as practicable, be uniform throughout Australia; and
>
> (f) that uniformity could best be achieved by the enactment of legislation by the Parliament of the Commonwealth as a law for the government of the Australian Capital Territory and the adoption of that legislation by the Parliaments and legislatures of the States and the Northern Territory

Recognition of points (a) and (b) in the long title suggests that Australian Governments were concerned with market failures arising from externalities and the public good characteristics of the environment. Recognition of point (c) turns on trade issues and potentially industry assistance issues, such as the support of the local industry and protecting the trade reputation of Australian products using AgVet chemical products as inputs.

According to a 2008 report by the Productivity Commission, there are potentially several sources of chemical-related market failures. Market failures

essentially arise because allowing parties to act solely in their own private interest may not lead to the best possible outcome. Some general sources of chemical-related market failure are:

- Externalities— for example, when chemicals discharged from a farm cause pollution and/or health problems for farm workers or downstream;
- Information failures— individuals may lack the expertise and or information to make fully informed decisions about the use of or disposal of chemicals; and
- Public goods— measures that protect human health and the environment can be underprovided by the private sector because 'free riders' cannot be excluded from enjoying the benefits, and therefore sufficient returns cannot be captured by those providing them to justify their investment.

Therefore, there is a case for regulating chemical risks, if it can be demonstrated that this is the most cost effective form of government intervention and that it would materially improve community wellbeing and that the benefits of the intervention exceed its costs.

The Productivity Commission's recent research study into the regulation of the chemicals and plastics industry also pointed out that the regulation should wherever possible, be light handed and commensurate with the risk. Pointing out that:

> There is more likely to be a net benefit if regulation is tailored to the *risk* posed by a chemical in a particular circumstance (its use), rather than the blunter approach of intervening whenever there is a *hazard* (Productivity Commission, 2008).

It is not difficult to think of examples where the production of or use of chemicals may lead to market failures that result in a detrimental effect to human health, worker safety, or the environment. However, there are no clear economic arguments to substantiate government interference to address issues related to the efficacy of products and to ensure that these are not unduly prejudicial to international trade.

Some may argue that issues related to efficacy may fall under the heading of 'information failures' and may therefore require government intervention. However, basic economic principles suggest that information failures are, instead, related to consumers lacking the information needed to assess the possible risks posed by particular chemicals. This information may be carefully guarded by producers and importers who lack the proper incentives to make it widely available (Productivity Commission, 2008).

Information failures, thus, cannot be applied to product efficacy. In this respect, firms should have the proper incentives to make sure that their product does what it is intended to or otherwise they may suffer the consequences of a loss in revenue— this is a fully internal cost and, thus, not a

source of market failure. Importantly, the only foreseeable role of government in this case is to establish a transparent legal system so that consumers may be fully compensated by firms in such cases. Establishing an efficient and transparent legal system is analogous to providing a public good, yet this is unrelated to government regulation of the chemical industry.

An efficient and transparent legal system that holds companies to account for any economic damaged caused by their products provides considerable incentives for companies to take steps to prevent this damage from occurring. The considerable penalties awarded against ICI following the Helix (endosulfan) contamination of beef, provides a powerful incentive for companies to ensure their products do not cause unintended consequences.

However, the Helix endosulfan case also demonstrates the significant costs incurred by those not party to the intended use of the product when something does go wrong. Some would argue that the costs of regulation are low compared to the cost and possible frequency of the damages that may be incurred by inefficacious products. This argument is more convincing when the damage is considerable and irreversible, for example complete crop failure leading to the collapse of a farm business. This argument is predicated on the assumption that there would be a greater number and more serious product failures (and hence greater economic damage) if efficacy was removed from the registration process.

Compulsory efficacy testing may lead to more product failures as the regulator may crowd out commercial incentives to demonstrate and demand efficacy information. Mandated efficacy may reduce a farmer's scrutiny of the product and the manufacturer reputation prior to purchase. In the absence of efficacy testing a farmer may look beyond the label and consider the capacity of the company to meet any claims against its products should they arise. Thus, in this situation the regulation may induce farmers to take bigger risks with the products they use and the companies they purchase products from than they otherwise would.

Overall there appears to be a weak rationale for compulsory efficacy testing for all products. A full cost benefits analysis should be undertaken to determine the likely affects of compulsory efficacy testing and the likely level of product failures if efficacy testing was left to market participants.

In regards to ensuring that the products used are not unduly prejudicial to international trade, economic theory suggests that it is the responsibility of export-oriented firms to ensure that their products meet international standards and that their products and supply chains do not unduly affect others. Again, if they do not they may suffer the consequences of a fall in export revenue or demands for compensation— which will be fully

internalised by the export-oriented firm. In other words, there is no clear economic reason as to why the APVMA may intervene in this area even if its role is only an advisory one. Therefore, the issue of *'furthering of trade and commerce between Australia and places outside Australia*' should be revised in future considerations of the role of the APVMA.

Regulation of AgVet chemicals to promote Australia's agricultural export trade, rather than the protection of human health and the environment has the potential to impose additional costs on some exporters if the APVMA's role is not clearly defined. This is because compulsory generic trade standards such as maximum residues limits (set to meet trade rules rather that reduce human health risks) may impose limits that are not required from some markets. The concern in regard to the APVMA is that section (c) of the legislation is not clear on this principle.

Regulated trade standards should be predicated on the risk:

- that some producers will be affected by the adventitious presence[8] of products that lead to a breach of delivery standards; and
- that recompense from those responsible for any economic loss is not possible.

In economic terms, these effects are externalities, or spillovers, as they affect others not party to the transaction or market where the agricultural product is traded. There are no prices attached to these effects. In the absence of an obligation to compensate stakeholders via legal liability or other mechanisms, some producers may not take these effects into account in making decisions to use AgVet chemicals and supply agricultural products to export markets.

Australian agricultural supply chains are capable of high levels of segregation of a range of agricultural products at low cost. For example the capacity to segregate a wide variety of grains has been repeatedly demonstrated in numerous studies of the grain supply chain as part of deliberations over the introduction of GM canola. There are also a range of food safety and eating quality standards applied by the red meat industry.

Where economic damages are incurred as a result of adventitious presence causing products to fall outside delivery standards, there appears to be ample capacity to resolve disputes or seek redress through the courts. Again this has been demonstrated by the numerous studies conducted on the effects of the commercial release of GM canola (ACIL Tasman 2005, Kershen 2002). Also current segregation systems for a range of non-GM traits are underpinned by common and contract law principles.

[8] Adventitious presences is the unintended presence of one product in another

There does not appear to be a strong economic argument to support the inclusion of chemical regulation to ensure their use is not unduly prejudicial to international trade based on the proven ability of Australian supply chains to manage high levels of segregation at low cost.

The only clear role for government is to ensure that the information regarding trade standards, as set up by international conventions— such as the Codex Alimentarious Commission (international MRL standards) — are made widely accessible to the public. Moreover, government could more extensively apply and recognise international health and environmental standards. This would both lower the cost of regulation in Australia and ensure exporters that their products will not encounter barriers in most foreign markets[9].

Duplication

According to research presented in the Productivity Commission (2008) report on chemicals and plastics regulation, there is a widespread belief among industry members that a major impediment to maintaining sustained growth in these industries is the existence of multiple regulatory authorities. According to the Chamber of Commerce and Industry of Western Australia (cited in the report):

> ...the existing system often gives rise to inequalities between businesses across state borders, and adds to business processes and costs where businesses operate in multiple states (Productivity Commission, 2008, p. XXVII).

The Productivity Commission (2008) continues by highlighting that in light of these difficulties a case can be made for national uniformity in setting broad policies, undertaking hazard and risk assessments and setting risk management standards and codes. This is especially so given that there is little need for technical codes to vary across jurisdictions because hazards and assessment methodologies are universal and, although risks can vary by location and use, appropriate breadth of scope and flexibility of implementation can be incorporated into a national regime. Moreover, interstate trade can be facilitated by a uniform approach to the transport, labelling and control-of-use of chemical products.

There is, however, another source of duplication which can arise from the APVMA undertaking tasks that are better suited to other government organisations. The following section discusses this source of inefficiency.

[9] See Productivity Commission (2008) for further discussion.

Consumer Protection and Effectiveness

As mentioned above, as part of the registration process for AgVet chemical products, the APVMA has responsibility to ensure that AgVet chemical products registered for use in Australia are efficacious or work effectively. A critical issue for the continuation of the APVMA registration process is whether an assessment of efficacy is actually required. This is because the specific regulatory requirements of the APVMA registration process for AgVet chemical products in its assessment of efficacy overlap with generic fair trading and consumer law. The existence of this overlap raises the policy question of whether generic fair trading and consumer law is adequate on its own to address concerns currently addressed by the APVMA registration process in relation to efficacy.

The Productivity Commission, in its recent review of Australia's consumer policy framework, has warned that there are fundamental deficiencies in the specific regulatory component of the policy framework that are detracting from good outcomes for consumers and the community (Productivity Commission, 2008, p. 88). According to the Productivity Commission, this has arisen due to a number of reasons:

- a need to supplement the generic consumer law is not always clearly demonstrated – with industry-specific consumer regulation sometimes introduced mainly because of a reluctance to enforce generic law and/or a lack of resources to do so; or to provide quick responses to problems raised by a vocal interest group
- some specific regulation is overly prescriptive, reducing the responsiveness of suppliers to changing needs to customers and increasing costs and therefore prices.
- certain regulations appear to be primarily designed to protect existing businesses from competition, rather than to assist consumers. (Productivity Commission, 2008, p. 88)

The Productivity Commission has expressed the view that a reliance on specific licensing requirements rather than generic consumer law is most likely to confer net benefits where the potential consumer detriment from making a poor choice is significant and:

- the costs of obtaining product information are high; and/or
- verification of quality by the consumer or other third parties is difficult. (Productivity Commission, 2008, p. 93)

Information on the effectiveness of the AgVet chemical products is in most instances evident to the user. This is particularly so for herbicides where the effect on the target weeds of the application becomes evident. Animal health products are similar as efficacy in fly strike and lice control is clear to

determine, as are internal parasites, where animal condition can be observed and faecal egg counts used after application of the product.

However, control of parasites in companion animals may not always be obvious. Where efficacy of the product is not clear, information asymmetry may be claimed and used as justification for intervention. Animal welfare needs also to be taken into account. If a product does not work, then the animal may continue to suffer the effects of the parasite until the owner becomes aware of the failure.

Efficacy of vaccines is not likely to be known until the animal is challenged by the disease and therefore information asymmetry could be high.

Where the capacity of the operator or owner to be aware of the efficacy of the product is limited there are a variety of agronomy and veterinary services, some of which are provided by State Government Departments, available. These services are widely used by most farmers and it is doubtful whether the cost of obtaining product information for AgVet chemicals is prohibitively expensive or the verification of quality is so difficult as to require an assessment of efficacy by the APVMA.

On this basis, it is arguably the case that much of the efficacy assessment undertaken through the APVMA registration process is needlessly duplicating protections already afforded through generic fair trading and consumer law.

In instances where a case of unacceptable risk of information asymmetry is established, a more efficient approach would be an appropriate response on a case by case basis. That is, only those products were there are reasonable grounds of a risk of information asymmetry that could lead to significant costs being incurred or the welfare of animals diminished; efficacy testing could then be included as a condition of the granting of a license.

Generic Fair Trading and Consumer Law

The foundation for fair trading and consumer law in Australia is provided by Part V of the Trade Practices Act 1974 (TPA) with the States and Territories adopting similar provisions in the early 1980s (Spier, 2007, p. 1). Part V, Division 1 of the TPA contains a number of provisions that provide protection against various types of conduct including the following:

- Section 52 is a general prohibition against misleading and deceptive conduct, or conduct likely to be misleading or deceptive
- Subsection 53(a) prohibits the making of false representations that goods are of a particular standard, quality, value, grade, composition, style or model or have had a particular history or particular previous use

- Section 55 prohibits a person from engaging in conduct liable to mislead the public as to the nature, manufacturing process, the characteristics, the suitability for their purpose or the quantity of any goods.

The Australian Competition and Consumer Commission (ACCC) is an enforcement agency, which can bring civil proceedings for breaches of the TPA. Contraventions of the provisions of Part V, Division 1 of the TPA are subject to civil sanctions and remedies. Remedies available for breaches of these provisions include injunctions to prevent the prohibited conduct continuing or being repeated or to require some action be taken, damages, probation orders, community service orders and corrective advertising orders, and ancillary orders of various kinds in favour of persons who have suffered loss or damage because of the conduct.

Individuals and corporations can bring private actions in any competent jurisdiction for breaches of Part V, Division 1 of the TPA seeking damages, injunctions, or ancillary orders. However, only the ACCC can apply for a court order seeking corrective advertising. The objectives of the penalties and remedies available are to provide for compensation for persons who have suffered loss as a result of contravening conduct, prevent the continuation of the contravening conduct, deter the wrongdoer from re-offending in the future (specific deterrence), and deter others from engaging in such conduct (general deterrence) (Australian Competition and Consumer Commission, 2007, p. 173).

In addition, criminal sanctions apply in relation to breaches of Part VC of the TPA, which for the most part contains criminal offences for breaches of provisions replicating most of the provisions contained in Part V, Division 1 of the TPA (with the exception of section 52). Monetary penalties of up to $220,000 for individuals and $1.1 million for companies apply for breaches of the provisions of Part VC of the TPA. In addition, adverse publicity orders, probation orders, community service orders and corrective advertising orders can be sought in relation to contraventions of Part VC (Australian Competition and Consumer Commission, 2007, p. 174).

Only the Director of Public Prosecutions can prosecute an offence under Part VC of the TPA and seek to impose a monetary penalty. The ACCC, however, can bring representative actions for breaches of the provisions of Part V, Division 1 and VC of the TPA seeking compensation for persons identified as having suffered, or likely to suffer, loss or damage as a result of the breach and who would otherwise have had to bring action of their own (Australian Competition and Consumer Commission, 2007a, pp. 5-6). To bring a representative action under the TPA, the ACCC must receive the consent of the persons concerned in writing prior to making the application. Similarly, if several individuals have each suffered injury, loss or damage as a result of

similar conduct in breach of Part V, Division 1 of the TPA, amendments in 1992 to the Federal Court of Australia Act 1976 permit a person to take a representative or class action in the court on behalf of a group of seven or more such persons.

There would appear to be ample protections afforded through the TPA in relation to the use of AgVet chemicals to enable the efficacy assessment undertaken by the APVMA to be eliminated.

Common Law

In addition to generic fair trading and consumer legislation at the Commonwealth and State level, protection against an ineffective AgVet chemical may also be provided through the common law.

Manufacturers and distributors of AgVet chemicals owe a duty of care to product users and others affected through the use of a chemical. In the event that an AgVet chemical caused physical injury, damage or economic loss then it may give rise to a breach of duty of care that could be the basis for a claim of negligence under the common law. However, an obligation of duty of care probably does not extend to the efficacy of an AgVet chemical.

Notwithstanding, contract law may provide the means through which persons can seek redress against ineffective AgVet chemicals under the common law. Implied terms relate to the provision of a contract that is not stated but nevertheless forms a provision in the contract. It is arguably the case that an AgVet chemical should adequately perform the function that its manufacturer and/or distributors claims, thus constituting an implied term within any sales contract for the product. Failure of an AgVet chemical to adequately perform the function that its manufacturer and/or distributor claims could give rise to a breach of contract action under implied terms in that the product should actually do what its manufacturer and/or distributor have claimed that it does.

There would appear to be protections afforded through the common law to ensure the efficacy of AgVet chemicals, although there may be less certainty surrounding these protections than those provided through Part V, Division 1 and Part VC of the TPA.

On the other hand, there may be some significant costs involved with having information asymmetries when it comes to medicines for both humans and animals. In the long-run consumers will vote with their wallets. They will decide not to buy a product that they have found not to work. In the short-run, however, buying inefficacious products may lead to animals getting sicker and perhaps dying. This could certainly be associated with costs related to losing certain assets (a prized bull or horse) or a pet. In this regard there may

be grounds to argue that efficacy could be a justifiable activity for animal medicine regulation.

6.3 Productivity Commission recommendations

The Productivity Commission's study of the regulation of chemicals and plastics made a number of recommendations pertinent to the appropriateness and effectiveness of the APVMA.

The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:

- *the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned*
- *its assessment priorities are directed to the most efficient management of the aggregate risk of all AgVet chemicals.*

The APVMA should regulate the use of agricultural and veterinary chemical products after the point of retail sale through amendments to the AgVet Code.

Currently control-of-use regulation is undertaken at the state and territory level and leads to inconsistency and inefficiency in the national market. In regards to cost recovery, the Productivity Commission also recommended with respect to NICNAS that the Government should pay for reviews of past chemicals.

The Australian Government should meet the cost of screening all existing chemicals from budget funding. NICNAS should continue to recover the costs of subsequent assessment of chemicals of concern.

6.4 The cost of APVMA regulation

As mentioned above there may exist some significant costs associated with regulation. In the presence of market failure society must aim to regulate industries up until the point where the marginal cost of regulation equals the marginal benefit. Any regulation beyond this point will result in a net welfare loss to the community.

There is a substantial literature on the economic costs (and benefits) related to regulation[10]. In this section we concentrate on some of the specific costs related to APVMA regulation as discussed in the Australian literature.

[10] For a comprehensive study see Parker (2002).

A recent report on the competitiveness of the animal health industry in Australia has found that a significant number of companies believe that the Australian regulatory framework creates problems for them because it:

- increases development time (75 per cent)
- increases the costs of development (67 per cent)
- creates significant uncertainty (67 per cent)
- re-directs resources into defensive R&D (58 per cent).

Moreover, the study found that between 2001 and 2006, animal health companies in Australia complained that the regulatory environment increased the average length of time needed to develop a major new product for food producing and companion animals by over a year (Business Decisions, 2007).

Additionally, that study found that regulatory factors have caused the average cost of developing a major new product for the livestock sector to increase by around 35 per cent in real terms between 2002 and 2007. Simultaneously, surveyed industry members indicated that regulatory factors have caused the average cost of developing a major new product for pets to increase by around 25 per cent in real terms over the same period (Business Decisions, 2007).

Similarly, the Productivity Commission (2008, p. XXXI) notes that firms incur significant costs in having chemicals assessed by the APVMA,

> The costs include the lengthy time involved, the expensive data requirements (which often duplicate international assessments) and the risk adverse approach adopted by the assessment agencies. The small size of the Australian market restricts the ability of firms to recoup these costs. Accordingly, some businesses claim that they are deterred from introducing new chemicals that may be more beneficial to users and the environment than the chemicals currently used.

It is important to make this link between the regulatory environment and the size of the industry in light of recent survey evidence indicating that 92 per cent of firms in the Australian animal health industry complain that the small size of the domestic market creates the most significant obstacle to innovation (Business Decisions, 2007). Hence, the chemical industry regulatory framework in Australia would do well in adopting cost-benefit (or risk-benefit) trade-off standards, which take into account the size of the domestic market and its effect on innovation[11].

The possible negative effect of regulation on innovation is important as it may be hindering the growth prospects of the industry. Business Decisions (2007) noted that the number one determinant of sustained long term growth in the

[11] This has also been suggested by the Productivity Commission in its aforementioned 2008 report.

animal health industry is product innovation. Interestingly, the report also found that nearly two-thirds of animal health companies in Australia have made a strategic decision to focus on older or existing technologies, rather than innovative technologies. It is concluded that in the majority of cases (67 per cent), regulations have played a major part in this decision.

The Productivity Commission notes that, in light of these difficulties, the timeliness and data costs of assessments could be greatly reduced through the adoption of appropriate overseas schemes and more extensive utilisation of international data and modelling tools (Productivity Commission, 2008) where possible.

7 APVMA's Cost recovery scheme

Cost recovery broadly encompasses fees and charges related to the provision of government goods and services (including regulation) to the private and other non-government sectors of the economy. According to the Financial Management Group of the Department of Finance and Administration, the Australian Government adopted a formal cost recovery policy with the aim of improving consistency, transparency and accountability and to promote the efficient allocation of resources (Financial Management Group, 2005).

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 (APVMA, 2005). The APVMA applies this policy to its three key activities by requiring a combination of fee and sales-based levy payments. The three key activities are:

- Monitoring ongoing compliance with regulation,
- Investigation and enforcement, and
- Registration and approvals.

In each case, the payments are made by firms in the industry. This is because it is argued that 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.

The APVMA uses a combination of fees and sales-based levies in its cost recovery scheme for two reasons. Firstly, in order to minimise the costs to Australian Government by recovering 100 per cent of the costs. Secondly, as discussed above, to ensure that small businesses and low volume chemical products do not face large disincentives from entering the market. It would appear, based on data from the previous CRIS, that the charging structure has

certainly achieved this later objective, but the benefits and the costs are far from clear.

The APVMA charges a nominal fee of 40 per cent of the cost of assessing applications for approvals and registration, 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 (APVMA, 2005).

The rationale for this approach is that a higher level of cost recovery via an 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 (APVMA, 2005).

However, this approach clearly results in a significant level of cross subsidy across products, which appears to have little if any link to the level of risk associated with the various products. That is the management of the environmental and social risk of the product and monitoring of this are not aligned with the costs of gaining a license from the APVMA. Moreover, the levy does not take into account variation in demand for products as it is based on future sales, while simultaneously having no cap and no finishing period. Consequently, a small number of high sales products will pay for themselves many times over and low/no sales products will never pay for themselves. This is important in light of evidence indicating that demand and thus revenue fluctuations can be severe due to factors such as the drought.

Table 4 **Summary of APVMA activities and charges**

Activity	Fee	Levy
A. Monitoring Ongoing Compliance with Regulation		
Manufacturer's Licensing Scheme	Annual Licence Fee	
Quality Scheme for Agricultural Active Constituents		Flat % rate levy
Adverse Experience Reporting Programs		Flat % rate levy
Chemical Review Program		Flat % rate levy
B. Investigation and Enforcement		
Investigation and Enforcement	Fee	
C. Registration and Approvals		
Registration and Approvals	Nominal Fee (applied at rate of 40% cost recovery)	Tiered levy based on disposals
Permits (minor use)	Nominal fee for administrative costs	Tiered levy based on disposals
Permits (research)	Nominal Fee (applied at rate of 40% cost recovery)	Tiered levy based on disposals

Note: This information is a reproduction of Table 7.

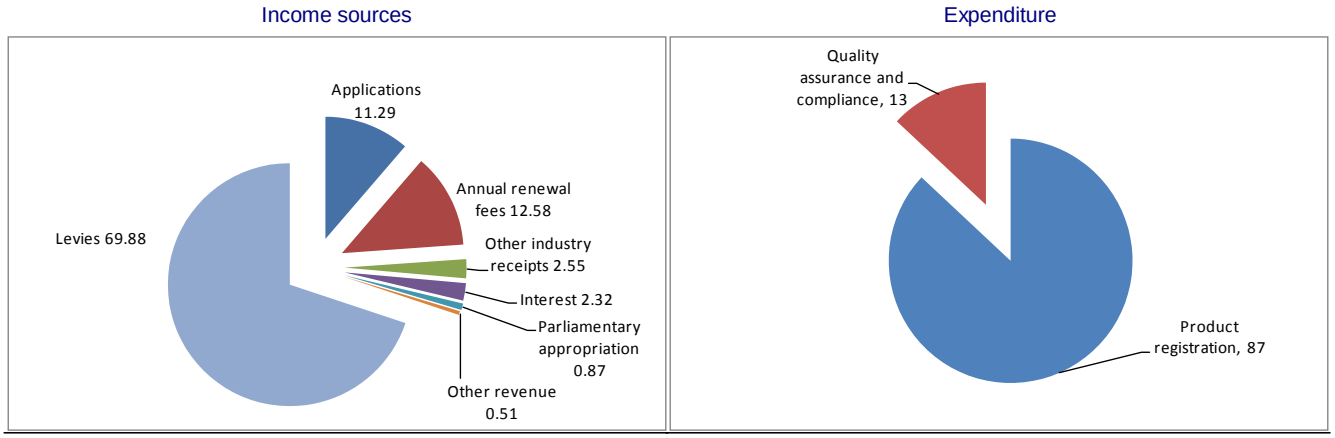
Data source: APVMA (2005)

In its 2006-07 Annual Report the APVMA reports

- Income of $25,330,020
  - 69.88 per cent sourced from levies
  - 11.29 per cent sourced from application fees
- Expenditures of $23,241,802
  - 87 per cent of expenditures were associated with regulatory decisions and information (product registration)
  - 13 per cent associated with chemical product quality (quality assurance and compliance).

It is also worth noting that while the fee structure specifies a split of 40 per cent up front and 60 per cent collected over the life of the product as levy, the actual split and total costs cannot be known upon application. This is because the total levy revenues are based on future sales, which also cannot be known at the time of application.

Figure 3 **Sources of APVMA Income and Expenditure (%)**



Data source: Australian Pesticides and Veterinary Medicines Authority, 2006-07 Annual Report.

The Productivity Commission reports that the APVMA has enjoyed surpluses from its cost recovery arrangements:

> APVMA operates on cost-recovery principles and is principally funded via a levy imposed on sales of registered AgVet products[12] and via application and annual registration fees. APVMA also collects licensing fees from manufacturers of veterinary medicines. In 2006-07, total revenue amounted to $25.3 million, of which $17.7 million, or around 70 per cent, came through the sales levy. APVMA has recorded operating surpluses in 2005-06 and 2006-07 of around $3.1 million and $2.1 million respectively

[12] The levy applies to individual products and is tiered on the basis of value of the sales.

By way of comparison the Productivity Commission (2008, p.56) reports that the NICNAS, which has statutory responsibility to undertake scientific assessments of chemical risk to public health, occupational health and safety (OHS) and the environment, also operates on a cost recovery basis but only had an income of $8.6 million of which 69 per cent was obtained from registration fees.

7.1 Calculation and allocation of costs by the APVMA[13]

The APVMA's regulatory operations are funded on a cost recovery basis. The main fees that the APVMA charges are for product registration applications, an annual fee and a levy based on product sales. There are also a number of other minor fees. These are discussed in detail in this section.

The APVMA uses the Activity Based Costing (ABC) model to calculate and allocate costs. 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. 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.

7.1.1 Application fees

The cost recovery framework is based on the APVMA recovering 40 per cent of the cost of an application from the applicant. The remainder of the cost of registration is recovered through a levy based on sales revenue. The application fee payable depends on the type of assessment required for the particular application.

Currently there are 25 different application categories. Most of these 25 categories have set timeframes and fees. However a number of the categories

[13] Much of the information in this section comes from APVMA (2005a, p.22) and APVMA (2005b), other sources are specified.

will be assessed using a modular approach. The particular module that will apply for consideration of a particular application and therefore the fee, timeframe and data requirements depends on the level of assessment required (APVMA, 2005b).

Table 5 summarises a selection of applications and fees. Application fees vary substantially depending on the description of the application and how long it will take to make the assessment. For example, an application for registration of a chemical product containing an approved active constituent, and approval of the product label will incur a fee of $21,210, if:

a) there is a registered chemical product containing the active constituent; and
b) the chemical product is to be used on a major food crop; and
c) there are no relevant maximum residue limits; and
d) poison schedule classification is required.

This application has an assessment period of 15 months. However, a 15 month application for registration of a chemical product containing an approved active constituent, and approval of the product label will incur a cost of $31,750, if:

a) there is no registered chemical product containing the active constituent; and
b) a full assessment of the chemical product is required.

Table 5 **Table of selected application fees and assessment periods**

Column 1 Item	Column 2 Description of application	Column 3 Assessment period	Column 4 Fee ($)
Applications for approval of active constituent contained in a chemical product, registration of the chemical product and approval of the product label			
1	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product	15 months	48 860
Applications for registration of a chemical product containing an approved active constituent and approval of the product label			
3	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is no registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required	15 months	31 750

Column 1 Item	Column 2 Description of application	Column 3 Assessment period	Column 4 Fee ($)
Applications to vary a registration or label approval			
11	Application to vary particulars or conditions of registration or label approval where the variation is to extend the use of the chemical product to a new major food crop	8 months	14 260
Applications for approval of an active constituent			
15	Application for approval of an active constituent requiring a full assessment	12 months	23 430
Applications 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, 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	3 months	320

7.1.2 Annual fee

An annual fee of $390 per product serves to maintain each product's registration for a financial year. The fee is paid in advance and applies to all registered products regardless of sales (APVMA, 2005b).

7.1.3 Tiered levy

The tiered levy system applies for firms importing or manufacturing relevant chemicals. Payments have to be made on a yearly basis for the product to operate legally in Australia.

The system described in this section aims to protect relatively smaller firms in the market. The tiered levy system is based on financial year product sales. The system works as follows:

- 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 the next $4 million product sales, then a levy rate of 0.40% on the remaining product sales above $5 million.

The table below (Table 6) demonstrates how the levy system works in practice using a simple example. In the table we present eight different hypothetical firms, the first firm has relatively small sales revenue of only $1,000 p.a. The last firm has relatively higher sales revenue of $10,000,000 p.a. The purpose of the table is twofold. Firstly, it shows that firms with higher sales revenue must pay a much larger total amount to the APVMA, even though the regulatory costs incurred may be no higher, or even lower, than those incurred for registrations of products with low sales turnover. Secondly, the table shows how many years it would take for each of these firms to repay the total amount associated with registration.

According to information in the notes from the first cost recovery workshop held by the APVMA in July 2008, the total cost of registering a new active constituent is in the order of $250,000 (APVMA, 2008). Based on item 1, Table 5 of the Code's regulations, $48,460 is recovered from the application for approval of new active constituents contained in a product, registration of the associated product and approval of the product label requiring a full assessment of the actives and product. Consequently, a total amount of approximately $201,140 must be recovered from the levy system.

Table 6 shows that, under the current system, a firm that earns $1,000 of revenue from the registered product would require over 22,000 years to repay the full cost, while a firm that earns $10 million of revenue annually from the same registered product would repay the cost of application in four years. Clearly firms that earn significantly higher revenue from a registered product repay the costs of regulation in a shorter period of time.

Table 6 **Sales revenue and number of years until full cost recovery**

Sales revenue	Pay 0.9% on < and = $1 million	Pay 0.55% on anything above $1 million to $5 million	Pay 0.4% on anything above $5 million	Total amount paid per annum	Number of years need to recover $201,140
$1,000	$9.00	0	0	$9.00	22,349
$1,000,000	$9,000.00	0	0	$9,000.00	22
$2,000,000	$9,000.00	$5,500.00	0	$14,500.00	14
$3,000,000	$9,000.00	$11,000.00	0	$20,000.00	10
$4,000,000	$9,000.00	$16,500.00	0	$25,500.00	8
$5,000,000	$9,000.00	$22,000.00	0	$31,000.00	6
$6,000,000	$9,000.00	$22,000.00	$ 4,000.00	$35,000.00	6
$10,000,000	$9,000.00	$22,000.00	$ 20,000.00	$51,000.00	4

Data source: ACIL Tasman

Clearly applicants with very low (or no) sales revenue would never fully cover their registration costs nor do they cover the compliance activity cost of the APVMA. In effect, firms with greater sales would have to pay their registration

costs and compliance costs many times over in order to cover the costs of firms who register a product which presumably brings little or no value to the market – given sales are low or zero.

It is clear from this stylised example that the level of cross subsidisation is extremely high. Given that the system takes very little, if any, consideration of whether benefits exceed costs or whether the risks of a particular product's use would involve higher or lower ongoing compliance costs, it seems clear that the system is flawed.

There are no clear-cut economic arguments for supporting this policy. As discussed above, this cost recovery policy penalises firms that sell more popular or profitable products to ensure that firms that sell less popular registered products –survive‖. This form of protectionism leads to significant inefficiencies as valuable resources are diverted away from more valuable alternatives to:

- subsidise some firms, and
- maintain these firms afloat.

These inefficiencies are ultimately borne by users of the agricultural and veterinary chemicals. As many of these users operate in markets which offer negligible opportunities for price discrimination, the ultimate outcome is less competitive Australian agricultural industries.

7.1.4 Permit fees

Permits allow for unapproved uses of chemical or for research purposes, to agreed standards of safety and efficacy, and are consistent with APVMAs registration process. A fee of $320 must be paid for most permit applications except emergency use permits and some permits where a government agency is the permit holder. The latter applies when the Australian, State or Territory Governments apply for a permit in support of their core business[14]. Government agencies are, nevertheless, 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).

[14] Core business includes activities which are undertaken by officers of a government agency that are directly related to a control strategy being developed, implemented and communicated by that government agency. This includes activities relating to the management of exotic pests and diseases, or market access. There is no fee for permit applications relevant to such activities.

This fee will cover a portion of the administrative costs associated with considering the application. A small number of permit applications – including research permits – will qualify for modular assessment and fees (described above) (APVMA, 2005b).

Clearly these fees are far too low to recover the costs associated with compliance and the review of the long list of chemicals that were in use before the national scheme and APVMA were created. Again it is the tier levy system revenue that pays these costs. Again there is no link between the revenue received by the APVMA and the risks being managed.

7.1.5 Fees for administrative services

Full cost recovery will apply to most administrative services, including Certificates of Export that will be charged as follows:

Table 7 **Charges for certificates for exports, current AUD**

Certificate for export	Cost
Standard format	$115
DFAT authentication (if required)	Additional $20
Identical duplicate certificate - no DFAT authentication	Free (if requested at same time as initial application)
Identical duplicate certificate - DFAT authentication	$20 (if requested at same time as initial application)

Data source: APVMA (2005b)

Where any change to the certificate is required, the full fee will be payable (APVMA, 2005b).

7.1.6 Manufacturers' Licensing Scheme (MLS)

In general, a manufacturer's licence is obtained by paying a fee of $6,000 in equal annual instalments. An instalment of the fee for issue of a licence is due for payment on the day the licence is granted, and a further instalment is due for payment on each anniversary of that day.

Nevertheless, it must be noted that under certain circumstances the amount of the instalment of the fee due in the following year for the issue of a licence can be only $3,000. ACIL Tasman understands that this applies if the holder of the licence provides evidence, to the satisfaction of the APVMA, that the total notional wholesale value of all the veterinary chemical products manufactured in the financial year at the premises specified in the licence is less than $50 000.

7.1.7 Refunds

Fees refunds are generally based on the stage at which the application is withdrawn or rejected. That is, refunds are generally prorated on the proportion of the application process undertaken to the point of withdrawal or rejection. In some circumstances full refunds (excluding screening fees) are possible.

8 Cost recovery principles and their application by the APVMA

To assess the efficiency of the APVMA cost recovery policies and activities we have used as a guide the OECD's Best Practice Cost Recovery Guidelines for User Charging for Government Services (OECD PUMA, 1998). In addition to the OECD guidelines we have also applied the principles of cost recovery established by the Productivity Commission (PC) (Productivity Commission, 2001). The overarching recommendation of both the PC and the OECD is that cost recovery should be implemented for economic efficiency reasons, not merely to raise revenue (Productivity Commission, 2001, p. xxix). That is, cost recovery should be used to post incentives that lead to the most efficient use of resources.

The OECD recommends cost recovery policies should be assessed against 9 principles. They are:

- Clear legal Authority
- Consultation with Users
- Determine full costs
- Effective and efficient collection system
- Improve and monitor organisational performance
- Treatment of receipts
- Appropriate pricing strategies
- Ensure competitive neutrality
- Recognise equity considerations

Each of these is considered in more detail in sections 8.2 to 8.10 of this report.

A common theme of the OECD and PC cost recovery principles is that there should be clear alignment with the cost of providing the service, the price charged for it, and the purchaser of the service. As has been discussed in previous sections of this report, a major trade-off of the policy to support small domestic AgVet chemical companies is a reduction of the alignment of costs and services. To support small domestic businesses considerable cross

subsidisation occurs. This has considerable consequences for efficiency and is discussed in more detail in the following sections.

8.1 Commonwealth Government cost recovery principles

Many of the elements of the OECD's best practices are embodied in the Productivity Commission (PC) recommendations (Productivity Commission, 2001). In this report, entitled *Cost Recovery by Government Agencies*, the PC recommended that:

> Cost recovery charges should be linked as closely as possible to the costs of activities or products. Fees-for-service reflecting efficient costs should be used wherever possible. Where this is not possible, specific taxation measures (such as levies) may be appropriate but only where the basis of collection is closely linked to the costs involved. (Productivity Commission, 2001, p. XXIX)

In its report, the PC defined a cross-subsidy as something that occurs when one group of users pays for more than the costs of the services received, and the surplus is used to offset the cost of services provided to other users (Productivity Commission, 2001, p. 117). According to the PC, cross-subsidies have many adverse consequences:

> Cross-subsidies between different processes or different users may permanently disadvantage one group relative to another. Those who pay the subsidy may restrict their use of the product, reducing desirable consumption that would have taken place if products were appropriately priced. Conversely, those who receive a subsidy may be encouraged to use too much of the product. There may also be „flow-on' effects where the cross-subsidised services are inputs to other activities. (Productivity Commission, 2001, p. 119)

The PC concluded that cross-subsidies were undesirable on grounds of allocative efficiency and should usually be avoided:

> Cross-subsidisation can undermine efficiency and generally should be avoided. (Productivity Commission, 2001, p. XLIV)

In December 2002 the Commonwealth Government accepted the PC's recommendation that government cost recovery charges should be linked as closely as possible to the costs of activities or products (Minchin, 2002). The Commonwealth Government's most recent guidelines on cost recovery state:

> Any charges should reflect the costs of providing the product or service and should generally be imposed on a fee-for-service basis or, where efficient, as a levy. (Department of Finance and Administration, 2005, p. 2)

In regard to cross-subsidies, the Department of Finance and Administration comments that:

> Poorly designed levies can create the possibility of cross-subsidies between firms and/or industries. This possibility arises because a levy (whether a flat or proportional tax) applies to all members of a leviable group equally. If, within that group, some members utilise the resources of the regulator less than others, then they can end up subsidising those members that require more intensive regulation. (Department of Finance and Administration, 2005, p. 62)

While there has been a change in the Commonwealth Government since the cost recovery policy and guidelines were issued, the published guidelines are still current suggesting that the new Government has accepted the policy of its predecessor on cost recovery.

8.2 Clear legal authority

Identifying the clear legal authority to recover the costs in the manner in which the APVMA does is difficult. The current web of Acts that establish the legal authority of the APVMA to recover costs is difficult to follow and lacks transparency. The following extract from the 2005 CRIS demonstrates this point:

> *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 (APVMA, 2005, p. 18).

The economic and efficiency justifications for the amount and the method of collection are also difficult to determine from the publicly available information. The current cost recovery framework underpinning the APVMA registration charges are summed up in the 2005 CRIS.

In response to the National Competition Policy Review recommendations on cost recovery, the Australian Government established the Signatories Working Group (comprising representatives of the Commonwealth and State and Territory Governments). The SWG determined that the most appropriate and effective cost recovery model for the APVMA 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; removal of the minimum sales levy volume
- Removal of the levy cap
- The levy rate should be set as the balancing factor.

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

These recommendations are somewhat different to the simpler cost recovery NCPR recommendations:

- 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
- Application and other registration service fees be cost reflective.

However, while the framework for cost recovery is articulated in the 2005 CRIS (APVMA, 2005) there are no economic arguments to support 100 per cent full cost recovery or the structure of the current system. It appears as though precedent rather than sound argument is the sole justification used to support the 100 per cent cost recovery policy.

8.3 Consultation with users

At present the primary consultation process in respect to the cost recovery policy of the APVMA is the CRIS process. Within five years of the previous CRIS a new draft CRIS has to be published and interested parties are asked to submit their views on the cost recovery policy and its impacts.

Inter CRIS consultations with industry are generally regular with reasonable dialogue occurring between the APVMA and the AgVet chemicals industry. However, effective consultations require the APVMA to have the flexibility and incentives to respond to the results of consultations. An open ended cost recovery process where significant surpluses have been accumulated does not appear to be conductive to the posting of service oriented incentives in the agency.

8.4 Determine full costs

The APVMA uses an Activity Based Costing (ABC) model to allocate the costs of each activity of the agency to the services it charges for. The basis of the model is the percentage of time staff members spend on a particular activity.

Overhead (corporate, board and administration expenses) expenses are allocated using an average staffing level (ASL) model.

There is no reason to conclude that the models chosen are not an efficient way of cost allocation. However, inputs into these models are subjective and there is no information on how the inputs are derived.

8.5 Effective and efficient collection system

8.5.1 The effectiveness of the APVMA's cost recovery structure

The sales-based tiered levy cross-subsidisation system generates a series of additional costs to agricultural and veterinary chemical businesses with high turnover that are unjustifiable on the grounds of market failure or trade. The APVMA essentially taxes those businesses with registered products that perform better in the market place.

There are potentially significant welfare losses that will result from this practice. On the consumer side, it must be noted that in a competitive market firms will pass on all of the increased costs resulting from this policy to chemical users. As a result, farmers will be made worse off as they do not have the capacity to pass on higher input costs to their customers. As a result farmers will be less competitive and lose net income directly from facing higher chemical inputs costs or indirectly through producing less viable commodities.

On the chemical producer side, some firms will have the incentive to register products that may not necessarily generate large economic, environmental, or social benefits because the relative cost of having a product assessed is small. A major by-product of this is that there are an increased number of products being sent to the APVMA for registration. According to industry representatives interviewed by ACIL Tasman in August and September, 2008, this has already created a clog in the processing system, leading to an increment in the time needed to have a product approved or rejected.

Frivolous product registrations also divert the APVMA resources from the on-going review of chemicals in the market prior to the introduction of the national system.

Additionally, this system may lead to a general downturn in the long run growth prospects of the industry. The following section addresses this important issue with the use of a simple theoretical model.

8.5.2 Industry losses and cross-subsidisation

The purpose of this section is to use a simple economic model to highlight some key mechanisms that may lead to general industry losses as a result of a

sales-based levy or cross-subsidisation cost recovery registration system. Note that we use a simple model that is an abstraction from reality in order to simplify the analysis. Some key simplifying assumptions are:

- All firms produce exactly the same good
- The industry only produces one good
- All firms face the same price for the good they sell
- Firms only vary in terms of the costs they face, but are otherwise identical.

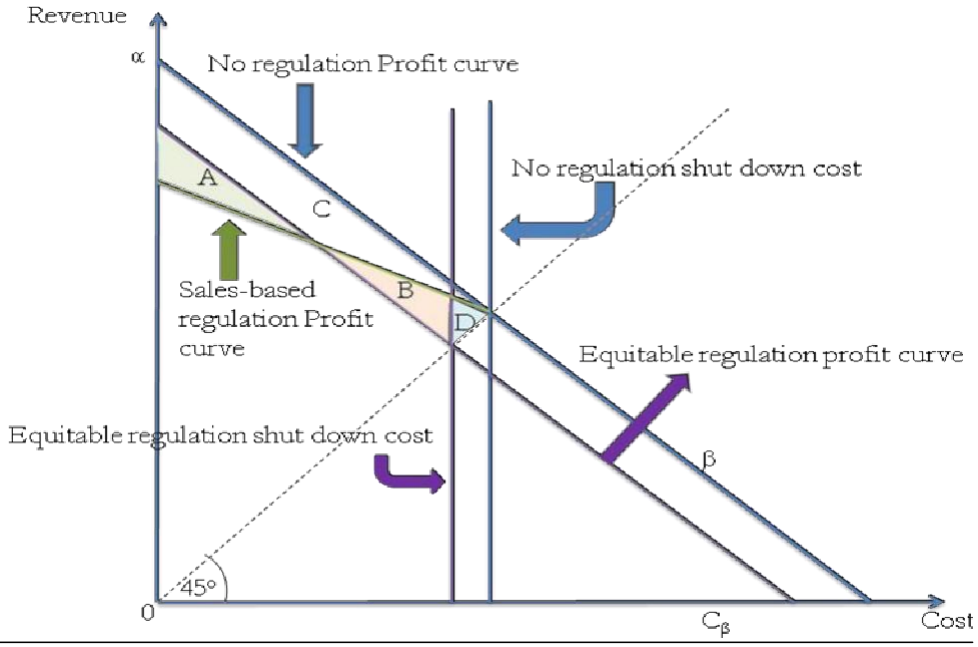
Figure 4 describes the model diagrammatically. The figure represents industry revenue on the vertical axis and cost on the horizontal axis. Assume that firms face zero production costs. In the absence of costs, Figure 4 would thus depict a horizontal line at point α. Defining profit as revenue minus costs, then in the absence of costs profit would be given by a horizontal line stemming from point α.

Assume in what follows that we add costs to the analysis. Moreover, let us take two points on the curve α and β. Let each point represent a particular firm. And assume that each firm produces one unit of exactly the same product, which faces the same price in the market.

As explained above, firm α has zero costs and therefore all of its revenue is categorised as profit. On the other hand, firm β has relatively higher costs (given by point C_β). Consequently, it faces much lower profits than firm α.

Figure 4 essentially captures a number of firms like α and β. That is, firms that produce and sell identical goods face different costs. Consequently, we are able to conjecture a profit point for each firm in the industry. By combining each point we can get a profit curve for the whole industry. Those firms that are to the left of the 45 degree line are relatively more profitable than those on the right. In fact, those to the right of the line face costs that are greater than their revenue stream. That is, they have negative profits. This is highlighted in the figure by the vertical shut down cost— any firm to the right of the shut down cost decides to no longer participate in the industry.

Figure 4 **Different cost recovery strategies and the industry**



Data source: ACIL Tasman

Figure 4 depicts three scenarios:

- No regulation,
- Equitable regulation, and
- Sales-based regulation

In the no regulation scenario firms face the blue profit curve and the blue vertical shut down cost curve. As explained above, those firms to the right of this cost curve are forced to shut down. In the equitable regulation scenario, each firm must pay 100 per cent of the regulatory cost associated with registering a good for consumption in the market. This essentially adds to the cost faced by each firm thus decreasing their profit stream— the industry faces a shift in the profit curve from the blue to the purple line. The overall effect of this is that the shut down cost faced by the industry decreases and more firms exit the market. The additional cost faced by the industry is categorised in Figure 4 as the sum of areas B, C, and D[15].

Consider finally the sales-based levy cost recovery regulation scenario. Here high turnover (and, by the nature of the assumptions used, more profitable) firms have to meet a proportionally higher burden than low turnover firms. In Figure 4 this is captured by pivoting the profit curve from the no regulation curve to the sales-based curve. In essence this creates an additional burden on

[15] Area D is also the deadweight loss of the scheme, which is the cost to firms that exited the industry as a direct result of the cost recovery scheme.

more profitable firms as depicted by area A. Moreover, this mechanism creates a _cross-subsidy' from more profitable firms to relatively less profitable ones. The transfer is depicted by the fact that the sum of areas B and D (the subsidy) is equal to area A (the additional cost).

On the whole, the sales-based cost recovery scheme has the effect of making the high turnover firms relatively less profitable. The implications of this for the growth prospects of the industry can be serious in light of OECD evidence suggesting that larger firms undertake proportionally more R&D than smaller firms (Symeonidis, 1996). This is particularly true for Australian firms (Thomson, 2008).

In other words, in an industry where R&D is the key source of future growth the sales-based cost recovery scheme can hamper growth prospects as R&D is expensive and larger firms tend to undertake the bulk of innovation.

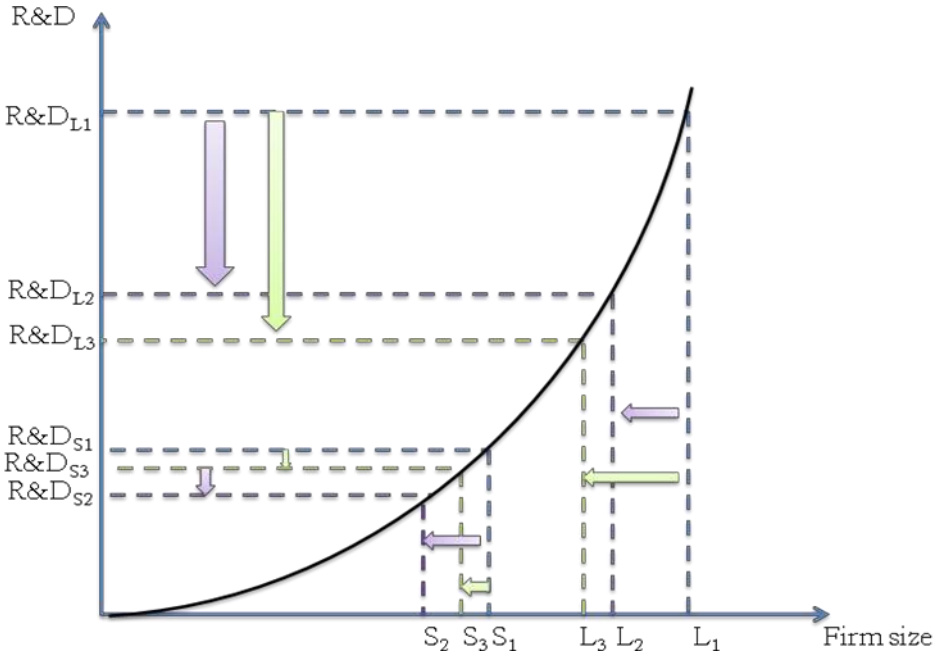
Figure 5 illustrates this point diagrammatically. For simplicity, the figure depicts an industry composed of two firms, one with a high turnover denoted as large (L) and one with a low turnover denoted as small (S). The horizontal axis in the figure represents the size of each firm. The vertical axis represents the amount of R&D each firm undertakes. The total amount of R&D undertaken by the industry is the sum of R&D done by both the large and small firms. The figure also depicts an upward sloping and convex relationship between firm size and R&D. The notion is that larger firms undertake more R&D both absolutely and in relative terms.

As in Figure 4, Figure 5 depicts three different policy scenarios. In the absence of regulation the large and small firms undertake investment in R&D equal to $R\&D_{L1}$ and $R\&D_{S1}$, respectively. As indicated above, the total amount of R&D undertaken by this industry is the sum of $R\&D_{L1}$ and $R\&D_{S1}$.

Consider that the regulator imposes an equitable cost recovery scheme. In this case each firm faces increased costs of production. This is captured in Figure 5 by a contraction of firm size from L_1 and S_1 to L_2 and S_2, respectively— note that the decrease in firm size is the same for both firms[16]. The effect on R&D, however, differs across the two firms. Since the large firm undertakes more R&D than the small firm in both absolute and proportional terms, a similar reduction in firm size will lead to a larger fall in R&D undertaken by the large firm than its smaller counterpart. Hence, total R&D falls from $R\&D_{L1}$ plus $R\&D_{S1}$ to $R\&D_{L2}$ plus $R\&D_{S2}$.

[16] This is a result of the assumption of identical firms with varying size.

Figure 5 **Firm size and R&D with different cost recovery schemes**



Note: Figures assume that there are only two firms— large and small— in the industry.
Data source: ACIL Tasman

The analysis of the so called equitable case foreshadows the outcome of adopting a sales-based cost recovery scheme. In Figure 5, the sales-based scheme leads to a further contraction in the larger firm as it faces increased costs. On the other hand, the smaller firm contracts by less in the face of cross-subsidisation from its larger counterpart. The overall effect of this is that R&D decreases further than in the previous case as the negative effect from the larger firm overwhelms the positive effect evident for the smaller firm. On the whole, total R&D in this scenario is given by $R\&D_{L3}$ plus $R\&D_{S3}$.

8.5.3 Efficiency considerations of the APVMA cost recovery system

The APVMA collection system is broadly split into a fee for service (the initial 40 per cent registration fee) and a trailing levy (regarded as a tax). Collection of the initial fee is an efficient and transparent way of cost recovery as:

- Consumers of the APVMA know what the cost will be in advance of the consumption of the service
- The fee is fixed
- The fee is efficient to collect as the administration costs for the APVMA and the company making the payment are low.

The levy on the sales of the products cannot be characterised in the same way:

- The total amount of the levy is not known in advance

- It is not fixed and is subject to variables outside the control of the company
- The amount of the levy that can be passed on to consumers of the products is not known and is subject to the competitive circumstances of the market
- Collection of the levy involves a _dead weight' cost of collection for the company and the APVMA.

In the absence of any clear market failure justification for an uncapped levy the dead weight costs of collecting are not offset by any public or private benefits gained.

8.6 Improve and monitor organisational performance

An open ended revenue stream is not likely to create incentives to improve services or find cost savings within the APVMA. Consultations conducted as part of this analysis have not indicated that the APVMA has reduced costs or improved services. There is no indication that the time taken to assess registrations has been reduced.

8.7 Treatment of receipts

The recommendation of the OECD for the treatment of receipts is based on several key principles that are relevant to the APVMA. They are:

- Consideration should be given to the relevant organisation retaining the proceeds of any user charges it collects. Such revenue should be classified as offsetting receipts (negative expenditure), as appropriate. This serves to reinforce the notion that users are paying a charge in return for a specific service and that responsibility for revenue management rests with the organisation itself.
- Consideration should be give to adopting flexible budgetary arrangements for organisations financed by user charges, which would allow them to respond to increased service volume by permitting commensurate increases in expenditure and user charges receipts (OECD PUMA, 1998, p. 12).

Both of these principles apply to the management of variations in income and expenditures by the agency providing the services. It emphasises the importance of having the flexibility to modify charges in response to changes in expenditure and income.

It is not clear that the APVMA cost recovery process has the flexibility to modify costs and charges in response to changes in expenditures or revenue. Without the capacity to modify the levy rate between CRIS cycles, revenues are entirely driven by sales values and volumes and not by service requirements or expenditures. This leads to the situation where large surpluses or deficits can be incurred by the APVMA. To manage this, a conservative cost recovery structure is likely to be introduced to prevent significant deficits in low sales

periods such as drought. This conservatism adds additional costs to the services charged for by the APVMA as surpluses need to be generated and carried forward.

This also causes the APVMA to have no control over the split in costs recouped between the fees and the levy.

8.8 Appropriate pricing strategies

8.8.1 Alignment of costs, services and clients

At present the APVMA applies a 100 per cent cost recovery policy. This policy is efficient if all of the costs incurred by the agency are the result of providing the service charged for. This does not appear to be the case as:

- some of the services provided by the APVMA are to inform the Government and provide information to other agencies and others. These activities are generally of a public benefits nature and are not a result of providing services to the licence applicants
- the APVMA cost recovery process is not aligned to the cost of services, rather they are aligned broadly with the sales performance of the chemicals licensed. This has resulted in the APVMA running considerable surpluses over the last few years.

It is difficult to see how 100 per cent cost recovery can be justified given that APVMA has legislative obligations to prepare information and consult with the Government on a range of matters, as typified in the following extract from the *Agricultural and Veterinary Chemical Administration Act 1992*:

> Section 7 (1A)(b): to provide information to the Governments and authorities of the Commonwealth, the States and the participating Territories about approved active constituents for proposed or existing chemical products, registered chemical products, registered listed chemical products, reserved chemical products and approved labels for containers for chemical products and to co-operate with those Governments and authorities on matters relating to the management and control of chemical products;
>
> Section 7(1A)(i)to exchange information relating to chemical products and their use with overseas and international bodies having functions similar to the APVMA's functions;
>
> Section 7 (1A)(j): when requested by the Minister, or on its own initiative, to report to or advise the Minister on any matter relating to chemical products or arising in the course of the performance of its functions;

The Section 8A of the Act also specifies that the APVMA must consult with the OGTR on a range of registration and label issues. The OGTR administers the licensing of GM organisms in Australia. The OGTR plays an important public interest role in the management of GM technology and GM organisms in Australia. The OGTR does not recover costs for its services which means

that there is potential for considerable cross subsidisation between the clients of the APVMA and the OGTR.

The APVMA also undertakes considerable international activities that are more of a public good nature, such as participating in health and environment standards forum and therefore should be funded from the public purse.

This is inconsistent with the recommendations of the PC cost recovery guidelines recommended in 2001:

> not using cost recovery to finance policy development, ministerial or parliamentary services, or meeting certain international obligations (Productivity Commission, 2001, p. XXIX).

Overall the cost recovery policy of the APVMA is open ended, leading to considerable surpluses being generated. Also there are a range of costs incurred by the authority that are not a result of providing services to licence applicants. This creates considerable cross subsidisation between the public and chemical companies applying for AgVet chemical licences. It is likely to lead to a range of perverse incentives and an inefficient allocation of resources within the APVMA and the AgVet chemical sector more generally.

8.8.2 Alignment of services and costs with the risks of chemical registration

Justification for the sales volume basis for the levy is based on an assumed correlation between the additional administrative and regulatory burden of higher volume products, as explained in the following quote from the 2005 CRIS:

> 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 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 (APVMA, 2005, p. 19).

However, adverse findings and the risk of externalities occurring are a function of the extent of use of the product and how dangerous the product is to the environment and society when not used appropriately. Thus, the APVMA charges have limited correlation with the risk of the externalities of the product's production or use.

At present the AgVet chemical registration process posts weak incentives for companies to reduce the risk of use or negative externalities of their products for the environment or society.

The flaws in the APVMA cost recovery policy are highlighted in the following quote from the PC 2001 report:

> Regulated firms may also react to the amount of cost recovery charges they incur, such as where charges are related to their output. But, in the case of pre-market regulation, firms basically have only a binary choice: to participate in the market and be regulated, or to decline to participate. They cannot choose how much regulation to consume at this stage. Charging for regulatory services can nevertheless have impacts on resource flows in the economy by altering industry costs and thus influencing industry size (Productivity Commission, 2001, p. XLI).

A more efficient cost recovery process would align the costs of registration with the externality risks of the products being registered. For example, registration charges could be based on a combination of the poison schedule of the chemical and the likely use having the lowest charge for low schedule products, low use, chemicals and rising for higher schedule, more risky use, patterns.

Basing fees and levies on the potential risk of the chemical would allow the AgVet chemical companies to choose ‗how much regulation to consume', and hence post incentives to reduce the risk of externalities of the products they are producing.

For companies to adjust their consumption of the regulation, the likely scheduling to be applied to the chemical would need to be known prior to the application being lodged. For existing scheduled chemicals the schedule is known. For new actives the APVMA should signal the criteria in advance allowing companies to make some prior assessment of the likely schedule that would be applied.

Basing fees and levies on the potential risks of the chemical would also create incentives for the APVMA to build capacity in identifying and managing the externalities of the chemical industry in Australia. This would improve the public benefits generated by this intervention.

8.9 Ensure competitive neutrality

Not applicable to the APVMA; generally the regulator does not provide services that are or are likely to be provided by a commercial operator.

8.10 Recognise equity considerations

The OECD Best Practice Guidelines suggest that:

- Consideration should be given to reduced charges for users where full cost recovery would represent an excessive financial burden on individual users.
- When a user charge does not represent full cost recovery, the degree of subsidy should be transparent to those providing and monitoring the service
- It should be recognised that measuring through the tax and benefit system [the levy] may be a more efficient means of ensuring equity than reduced charges.

While there are reasonable equity grounds for small variations of fees and levies to reflect the capacity of users to pay, there are significant efficiency tradeoffs with this policy. The current cost recovery policy of the APVMA appears to be excessively biased toward misguided equity concerns, which lead to significant reductions in the efficiency gains of the policy (see section 8.5.1 for a detailed discussion of the efficiency tradeoffs of the current policy).

In addition to the efficiency tradeoffs there are also significant inequities in the current policy, particularly in 100 per cent cost recovery.

The current cost recovery charges should be aimed at reducing reliance on general taxation revenue—that is consumers of regulated products should bear the cost of regulating them as far as it is practical to do so. Under the current APVMA system consumers and manufacturers share all of the costs of regulation even when the APVMA undertakes public good activities. Also consumers of the chemicals bear costs that are not related to the potential social and environmental risks of the product they are using.

9 Lessons from similar organisations

This section compares pricing mechanisms of three similar regulatory agencies to highlight certain key differences that may shed light on avenues of reform for the APVMA. The three regulators we take into consideration are:

- Wheat Exports Australia (WEA)
- Therapeutic Goods Administration (TGA)
- Office of the Gene Technology Regulator (OGTR)

Regarding the notion of cost recovery, this section shows that this policy option has been applied differently across these regulators. For instance, WEA makes no concessions to different organisations based on size or market power. On the other hand, the TGA (like the APVMA) aims to ensure that smaller players are able to enter the market. However, unlike the APVMA, the TGA does this by providing exemptions to smaller firms. Finally, the OGTR has decided not to pursue this policy as it has evidence to indicate that the size of this market in Australia is too small and additional costs may lead to an excessive number of firms shutting down.

This section also shows that in different cases the role of regulatory agencies changes. For instance, WEA aims at ensuring that international competition in wheat export markets abides by international laws and regulations. On the other hand, the TGA and the OGTR (like the APVMA) aim to ensure that goods that enter the Australian market will not cause undue harm to consumers or the environment. In what follows we review each agency in more detail.

9.1 Wheat Exports Australia

On 1 July 2008, Wheat Exports Australia (WEA) replaced the Export Wheat Commission. WEA's role is to regulate the export of bulk wheat from Australia through the bulk Wheat Export Accreditation Scheme (Bulk Scheme). Under the Bulk Scheme, WEA has the power to grant, suspend, cancel or vary bulk wheat export accreditations (WEA, 2008).

To become accredited under the Scheme, exporters are required to show they are fit and proper by demonstrating that they satisfy the scheme's specific eligibility criteria.

WEA is also responsible for:

- maintaining a public register of accredited wheat exporters
- monitoring the ongoing performance of accredited companies through an annual reporting system
- monitoring AWB (International) Ltd (AWBI), which previously held the single desk for Australian bulk wheat exports, until it achieves accreditation.

Funding of WEA is provided through application fees under the Bulk Scheme, as well as the $0.22 per tonne Wheat Export Charge, which is applied to all wheat exports from Australia. WEA charges a fee on a cost-recovery basis for the processing of applications under the Bulk Scheme. The Bulk Scheme sets out the following application fees:

- Accreditation application fee: $13,299 (Incl GST)

- Renewal of accreditation application fee: $7,084 (Incl GST)
- Variation of an accreditation application fee: $6,248 (Incl GST)
- Reconsideration of a decision application fee: $3,344 (Incl GST)

9.2 Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA), a unit of the Australian Government Department of Health and Ageing, carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an *acceptable standard*.[17] At the same time the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances (TGA, 2008).

Therapeutic products regulation is achieved through a risk management approach to pre-market evaluation and approval of therapeutic products intended for supply, licensing of manufacturers and post-market monitoring and surveillance. In this respect the regulatory model has many similarities with the APVMA.

The TGA regulates a wide range of medicines and medical devices including prescription and ―over the counter‖ medicines and blood and blood components and human tissues.

The TGA uses an activity based approach to cost recovery. The approach, while similar to the approach used by the APVMA, aims to recover costs at the time that they are incurred. For example, the costs associated with registration are intended to be recovered in the period in which the registration activity takes place. In other words there is no long tail of charges based on turnover as is the case under the APVMA cost recovery arrangements. Despite this the TGA includes a cost recovery exemption, which ensures that regulation does not impede certain low turnover products coming to the market.

The TGA cost recovery approach has to date not fully recovered the TGA costs intended to be recovered. However, the charging approach applied does use methods that attempt to align costs incurred as a result of the complexity of the evaluation activity being undertaken, with the cost recovery fees actually charged.

For example, in the case of non-prescription and complementary medicines, cost recovery charges include fixed and variable charges. Fixed charges cover registration fees and less complex evaluations. A variable fee is charged if an evaluation involves analysis of clinical or toxicological data, with the charge

[17] Acceptable standard means that medical goods including medical devices must be of acceptable quality, safety and efficacy.

being determined by the number of pages of clinical or toxicological data in the submission. In other words the number of pages in a submission is used as a proxy for the complexity and hence the cost involved in the evaluation.

Over the counter medicines and complementary medicines

The following tables (Table 2 and Table 3) summarise the TGA's cost recovery charges for 2008-09 for non-prescription –over the counter medicines‖ and complementary medicines.

Table 8 **Registration**

Cost Source	Fee ($)
Application fee	1,090
Additional /concurrent application fee	480
Processing fee (variation to an existing registration)	1,090
Annual charge	1,010

Data source: TGA (2008)

Table 9 **Evaluation fees per submission if the evaluation documentation does not contain clinical or toxicological data**

Cost Sources	Fee ($)
New product	7,230
Variation	2,610
New substance: CMEC, sunscreen excipients, all other	7,230

Data source: TGA (2008)

Table 10 **Evaluation Fees based on total page count(s) of clinical or toxicological data per submission**

Type of product	Page count	Fee ($)
New product **or** New substance **or** Multiple new excipients in listed or registered good for dermal use **or** Assessment of Safety and Efficacy	1-50	7,230
	51-250	9,260
	251-500	12,700
	501-1000	16,900
	1001-2000	25,300
	2001-3000	33,800
	>3000	50,600
Variations	1-50	2,610
	51-250	9,260
	251-500	12,700
	501-1000	16,900
	1001-2000	25,300
	2001-3000	33,800
	>3000	50,600

Type of product	Page count	Fee ($)

Data source: TGA (2008), http://www.tga.gov.au/fees/fees08.htm.

Low volume turnover declaration application fees

An exception to this cost recovery method is applied to applications where the product is expected to have a low value and low volume. Low volume turnover application fees apply to any therapeutic product (including registered and listed medicines) where the product annual charge exceeds 6.8% of the estimated or actual value of wholesale sales turnover of a product. The exemption aims to reduce the regulatory cost for products with very low circulation. For 2008-09, the low value, low volume, application processing fee remained unchanged at $120.

This low volume charge will involve cross subsidisation. However, it ensures that the cost recovery approach does not hinder certain therapeutic products which could have considerable value to certain members of the community from being brought to the market.

9.3 Office of the Gene Technology Regulator

The Office of the Gene Technology Regulator (OGTR) has been established within the Australian Government Department of Health and Ageing to provide administrative support to the Gene Technology Regulator. The regulator aims to protect the health and safety of Australians and the Australian environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (OGTR, 2008).

The OGTR does not apply a cost-recovery scheme. The OGTR has commissioned three reports on the cost-recovery options available to it[18]. The latest report commissioned, highlights some key reasons why the OGTR cannot successfully use a cost-recovery scheme (Acumen Alliance, 2004).

Acumen Alliance (2004) undertook a review of major stakeholders that may be affected by the introduction of a cost recovery scheme. It concluded that given the size of the market, the relevant firms would be unable to pass on the costs of regulation to consumers— the review found no evidence of substantial profits being made by this industry. Overall, this suggests that the imposition of a cost recovery scheme may lead to commercial organisations moving their operations abroad or applying their resources elsewhere. Acumen Alliance

[18] The reports are readily available from http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/kpmg-1

further indicated that this would be inconsistent with the Australian Government's support for this industry.

10 Conclusion

This analysis has concluded that:

- There are no clear systemic market failures apparent in the use of AgVet chemicals in Australia that justify the use of a combination of a fee and an uncapped levy based on the sales value of registered products:
  - The cost recovery approach used by the APVMA creates perverse incentives for products to be registered that may have little or any value to the Australian community.
- The current cost recovery system is not aligned to the externality risk of registered veterinary medicines and chemicals and therefore does not create any incentives for them to be better managed by the supplying companies or the veterinary medicines and chemicals consumers.
- There does not appear to be a strong economic case for the APVMA to include efficacy in the registration process.
  - However, where consumers do not have access to reliable and inexpensive information on products (particularly where animal welfare is an issue), there may be a justification for efficacy to be included in the registration process.
- A 100 per cent cost recovery policy (which under current arrangements can actually exceed 100 per cent) does not appear to be justified, given that the APVMA undertakes a number of Ministerial and public good tasks, many of which are prescribed in the *Agricultural and Veterinary Chemicals Code Act 1994 (the AgVet Code)* and the *Agricultural and Veterinary Chemicals Act 1994*.
- An uncapped levy system does not create incentives for the APVMA to be responsive to the industry's needs or to become more efficient in its delivery of regulatory, Ministerial and public good services.

Many of the flaws in the APVMA cost recovery process are attributed to the misguided attempt to correct perceived market failures in the Australian AgVet chemical industry. This has led to a complicated fee and levy system that promotes the registration of chemicals and products that would not be submitted for registration if the full costs of the process were borne by those registering the chemicals. That is, the current system does not ensure that the risk of registering a chemical that may not meet the market's requirements is borne by those making the application.

To improve the appropriateness and effectiveness of the registering of AgVet chemicals, the following broad principles should be applied to the process:

- The total costs of registering a product should be aligned to the risks of externalities occurring—chemicals that pose a higher risk to society and the environment (assessed on toxicity and potential for misuse) should attract a higher charge
- A fixed fee should be charged, with any additional costs capped
- A tiered charge could be established to ensure lower/special use chemicals are not disadvantaged
- The APVMA should monitor the information available to consumers of the product to ensure the market is fully informed of the efficacy of the products used
  - Where information asymmetry is identified, the APVMA should, as a last resort, include efficacy evaluation as part of the registration process.
- Cost recovery should be aligned to those receiving the benefits. There is a strong case for public contributions to be made to the APVMA to cover the costs of the APVMA Ministerial and public good activities.

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A APVMA licensing process

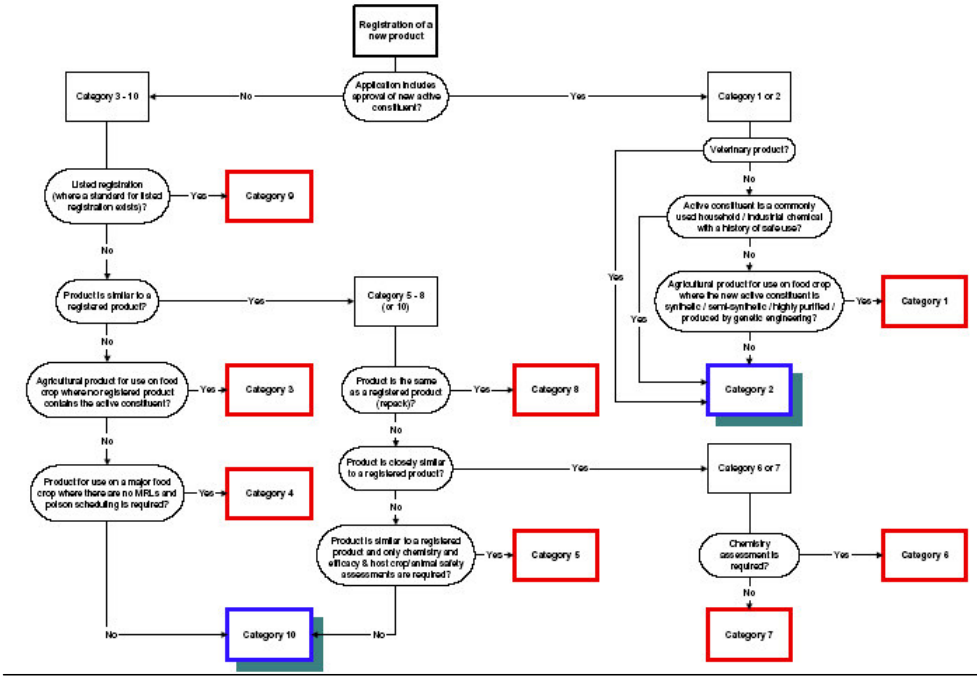
The licensing procedure for the registration of pesticides and chemicals is disclosed by the APVMA's Manual of Requirements and Guidelines (MORAG). With regard to agricultural and veterinary chemicals manufactured or used in Australia, MORAG sets out the Australian Government's requirements for:

- Approval of an active constituent,
- Registration of a product,
- Approval of a label, and
- Variation to an active constituent, product or label (APVMA, 2004).

MORAG is published in two versions, Ag MORAG and Vet MORAG. Each version contains information directly relevant to either agricultural or veterinary chemicals (APVMA, 2004).

According to a recent review of the APVMA registration process by Leesong (2006) of Organic Crop Protectants Pty Ltd, there are currently two general streams for registering products in Australia, which are defined by the classification of the active constituent. The product can be classified as of biological origin or artificially synthesised. The decision tree in Figure 6 describes the various streams or categories under which registrations proceed, depending on the product and the objective of the applicant. Most applications for new products are made under Category 2, which is a modular process. This process is more flexible and can save applicants considerable time and money. Category 1 comes with an upfront fee of $48,680 whereas the Modular process allows for a more –pay as you proceed‖ approach (Leeson, 2006).

Figure 6 **Decision tree for the registration of a new product**



Data source: This is a reproduction of Diagram 1 in Leesong (2006).