

**Product Integrity, Animal and Plant Health - APVMA**  
**Senate Rural and Regional Affairs and Transport Legislation Committee**  
ANSWERS TO ADDITIONAL QUESTIONS ON NOTICE

**Agriculture, Fisheries and Forestry Portfolio**

Additional Budget Estimates, 15 February 2005

**Question: PIAPH – APVMA Additional 09**

**Topic: Uhrig Report and APVMA governance**

**Hansard Page: NA**

Senator Heffernan asked:

You are aware of the Uhrig Report and the Government's initial response to Uhrig Report? I will quote from the Finance Minister's response (source below) "By applying the Uhrig templates to all government agencies, and thereby ensuring there are clear lines of accountability from the Minister down to the agency, the Government can implement better corporate governance in the public sector without the need for an additional layer of regulation. The assessment of all Australian Government agencies against the templates is expected to be completed by March 2006."

Source: <http://www.finance.gov.au/scripts/Media.asp?Table=MFA&Id=550>

What are Department's plans for undertaking this review for the APVMA? When will you be commencing?

Answer:

The Department will be reviewing the APVMA against the Uhrig template. The review is scheduled for the second half of 2005.

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**Question: PIAPH – APVMA Additional 10**

**Topic: Small Business and the APVMA**

**Hansard Page: NA**

Senator Heffernan asked:

- a. How many companies have products registered with the APVMA?

Answer:

A total of 801 companies currently have products registered with the APVMA. Based on sales figures provided to the APVMA as at 15 April 2005, a total of 728 of these companies are categorised as 'small' (turnover of less than \$5 million).

- b. How many products are registered with the APVMA by these 'small' companies?

Answer:

A total of 4,212 products are registered to the 'small' companies (companies with turnover of \$5 million or less).

- c. What proportion of these products are used in agriculture?

Answer:

A total of 2,607 of these products are classified as agricultural chemical products according to the Agricultural and Veterinary Chemicals Code (the AgVet Code).

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**Question: PIAPH – APVMA Additional 10 cont.**

**Topic: Small Business and the APVMA**

**Hansard Page: NA**

d. What proportion of these products are high risk? What proportion are low risk?

Answer:

The risk profile of a chemical per se (as opposed to the risk arising out of its use in accordance with label directions) will vary depending on whether the risk is examined from the perspectives of people, crops, animals, the environment and/or trade. Neither the Department or the APVMA is able to provide specific advice or generalise on the proportion of chemicals that are intrinsically “high risk” or “low risk” because of the different factors that apply in each situation making the same chemical higher risk for some and low risk for others. These various factors are considered by the APVMA in its risk assessment for each specific scenario and are addressed by means of the approved labels which include key instructions to mitigate particular risks.

e. How much did APVMA's defence of this matter cost (including officer resource time)?

Answer:

Assuming the question relates to the Administrative Appeals Tribunal (AAT) hearing in December 2004, the total estimated costs to the APVMA is \$61,225. This includes counsel fees and resources.

f. Would these costs ultimately be drawn from other companies participating in the Agvet chemical sector?

Answer:

Yes. These costs would be drawn from levy revenue.

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- g. Given the Administrative Appeals Tribunal's comment that – quote – "swimming pool disinfectants would not ordinarily be regarded as agricultural chemical products and their sale would not ordinarily be expected to be regulated by an Australian Pesticides and Veterinary Medicines Authority pursuant to an Agricultural and Veterinary Chemicals Code" – how many other categories of non-agricultural veterinary product is the APVMA attempting to regulate?

Answer:

The APVMA is obliged to regulate products which are included in the scope of its governing legislation (the Agvet Code).

The APVMA only regulates products that come within the definition of agricultural or veterinary chemical products provided by sections 4 and 5 of the Agvet Code and as prescribed in Agvet Code Regulations 7 and 8. In relation to the swimming pool products in question, the AAT confirmed in June 2004 that they met the definition of an agricultural chemical product in section 4 of the Code

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- h. What measures has the agency put into place to reduce the small business regulatory burden?

Answer:

The cost recovery framework implemented in the APVMA reflects government policy.

Both the old and new fee structures of the APVMA include measures to reduce the burden on small business. In particular, application fees provide a level of cross subsidisation that favours small business. All applicants will only pay 40% of the actual cost of the application the remainder being recovered by the levy. 100% cost recovery of application costs would result in application fees being prohibitive for many small businesses.

Other measures which assist small business include the recent implementation of new legislation allowing for listed registration or reservation from registration for products of low regulatory requirement. The APVMA is consulting with industry in achieving this objective.

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**Question: PIAPH – APVMA Additional 11**

**Topic: Agency Operating costs/expenditure**

**Hansard Page: NA**

Senator Heffernan asked:

An analysis of the APVMA revenue and expenditure since 1999/00 to the present shows both a significant increase in expenditure and a shift from profit to loss. Indeed, APVMA past and projected financial data show that it has been operating deficit budgets since 2001, and has consumed \$6.1M in reserves during the same period. Based on existing forecasts, APVMA will have effectively increased its expenditure by 52% by 2007/08 over the nine years (see table).

Financial Year	Revenue \$ Million	Expenditure \$ Million	Profit/Loss \$ Million	Reserves \$ Million
1999/00	18.538	16.223	2.315	8.465
2000/01	18.760	17.717	1.043	9.508
2001/02	19.764	20.624	(0.859)	8.648
2002/03	19.513	20.325	(0.811)	7.894
2003/04	18.1	21.6	(3.5)	4.4
2004/05	18.9	21.8	(2.9)	1.5
2005/06	24.26	23.26	1.0	2.5
2006/07	25.14	24.14	1.0	3.5
2007/08	25.67	24.67	1.0	4.5

This has occurred during a period when fiscal responsibility has meant many other critical government services have had to do more with less. It is doubtful whether the financial position outlined in the table would have been tolerated if APVMA were funded from consolidated revenue.

- a. Can the Department explain the mechanisms in place to ensure the application of Commonwealth financial management principles and budgetary restraint are being adhered to at the APVMA?

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Answer:

The APVMA is a statutory authority with the same corporate governance arrangements as other similar agencies. The Authority operates under the constraints of the Commonwealth Authorities and Corporations (CAC) Act and is subject to the other legislative requirements governing CAC Act agencies.

The APVMA's accounts are scrutinised each year by the Australian National Audit Office (ANAO) and the APVMA has always received unqualified audit reports from the ANAO.

An active Internal Audit program is overseen by the APVMA's Audit Committee which comprises three Directors appointed by the Board. The Board of the APVMA approves the budget and is responsible for the overall financial performance of the organisation. The annual Operating Plan is approved by the Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry each year.

In terms of financial reporting, the APVMA is subject to the same financial reporting requirements as other Commonwealth agencies. However, unlike other Commonwealth agencies, the revenue streams of the APVMA are not certain and will vary from year-to-year according to fluctuations in agvet chemical sales. For this reason, the APVMA aims to maintain a financial reserve comprising approximately three months operating expenses. This provides a responsible form of protection against fluctuations in agvet chemical sales.

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- b. Can the Department explain how this situation has arisen in light of the fact that APVMA had in excess of \$9.5M in reserves at the end of the 2000/01 financial year?

Answer:

Revenue has been declining over recent years particularly as a result of the drought and its impact on agvet chemical sales. For example, total revenue in financial year 2003-04 (\$18.1 million) was lower than that for financial year 1999-00 (\$18.5 million).

During the same period, there have been a number of unavoidable increases to key expenses such as insurance premiums, building lease costs and superannuation contributions. The APVMA has also undertaken additional program delivery functions to ensure it meets its legislative obligations. Some examples of these include the Adverse Experience Reporting Program for agricultural chemicals and implementation of new data protection and label approval legislation.



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- c. The Department recently circulated a Cost Recovery Impact Statement that sets out proposals to reform the cost recovery framework for the APVMA. The proposal also seeks to increase APVMA revenue to \$24.26 Million in 2005/06 (i.e. by about \$5.3 Million over 2004/05). The fact that all of the APVMA funding comes from industry – not government – does not justify unrestrained growth in agency size and costs.

Can the Department justify the increase?

Answer:

The major justification for the increase in revenue is the need for the APVMA to fully and properly discharge its legislative functions. Key areas of new or additional work activity include:

- A significant increase in numbers of applications for product registration and permits since 1998/99 (an average 330 extra per annum for the next 5 years);
- Increased process requirements following legislative change to require approval of final printed labels;
- Increased resource requirements to implement new data protection legislation;
- Full operation of the Adverse Experience Reporting Program (AERP) for Veterinary Products and implementation of AERP for Agricultural Products;
- Full operation of the manufacturers licensing scheme for veterinary medicines (now 230 fully licensed manufacturers compared with 117 in 2000);
- Strengthening of compliance activities to ensure only registered, safe and effective products are supplied in Australia;
- New programs to ensure the quality of agricultural chemical products and to better assess and communicate potential trade risks for Australian agricultural exports associated with the use of agvet chemicals; and
- A program to improve the availability for safe and effective chemicals for minor uses by Australian farmers.

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An increase in revenue is also necessary to enable the APVMA to meet its commitments in respect of a number unavoidable expenses such as normal increases in salaries and other operational costs, plus some abnormal changes to items such as superannuation contributions, building lease costs and increases to insurance premiums.

\$1 million of the \$24.26 million anticipated revenue in 2005-06 will be allocated to reconstitute the reserve.

- d. If the increase is to fund new programs, what scrutiny have these new programs been subjected to – are they subject to review by Treasury and/or Department of Finance?

Answer:

Under the APVMA's governing legislation, the APVMA prepares a Corporate Plan (3 years) and an annual Operating Plan which includes all proposed activities. These plans are closely scrutinised and endorsed by the APVMA Board. These Plans are approved each year by the Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry. They are not subject to review by the Department of Treasury of the Department of Finance and Administration.