Senate Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2010

Agriculture, Fisheries and Forestry

Question: APVMA 01

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: FOI requests
Hansard Page: 183 (24/05/2010)

Senator BACK asked:

Senator BACK—Excellent. Has there been a reduction in FOIs in the agency in the financial year which is coming to a close?
Dr Bennet-Jenkins—I would have to take that on notice. I do not have the FOI numbers. Just from memory, FOI requests are pretty steady; there is no increase or decrease. But I could get the exact number for you.

Answer:

The table below sets out the number of FOI requests the APVMA has received for each of the past six years.

	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10
Number of requests *	7	16	14	13	13	23	19

* An FOI request that was determined by a primary delegate and then internally reviewed by another delegate is counted as a single FOI request

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: APVMA 02

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Legal costs
Hansard Page: 184 (24/05/2010)

Senator BACK asked:

Senator BACK—Legal costs are issues that we have discussed with you in the past—$1.0 million, $1.4 million. Can you tell us what legal costs you anticipate in the coming financial year? Are you aware of any impending challenges that are going to have an impact on your budget from a legal cost point of view?
Dr Bennet-Jenkins—We are not aware of any impending legal challenges. I do not have the exact amount that we have set aside for next year's budget for legal costs. Again, we could provide that on notice.

Answer:

The total budget for the APVMA Legal Program for 2010/2011 is $1,110,000 comprising:

(i) $785,000 for the APVMA legal staff salary and superannuation
(ii) $250,000 for external legal advice; and
(iii) $75,000 for operating costs such as stationery, training and travel.

This budget includes all legal work including managing FOI requests.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: APVMA 03

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Carbendazim
Hansard Page: 131 (24/05/2010)

Senator XENOPHON asked:

Finally, the final report into the review of the management of carbendazim, when is that likely to come out?
Dr Bennet-Jenkins—The draft report—what we put out is a draft report—on the human health, the public health and occupational health side of things is likely to come out sometime this year. We are awaiting the draft report from the Department of Health and Ageing, who are writing this report for us. It will then go out for a period of public comment before we make the final decision. But because we had feedback of some certain concerns about the exposure assessments, in terms of residues as well as public health worker exposure, we took some suspension action quickly to remove those uses while we went through the public comment period and finalised the report.
Senator XENOPHON—So by September, do you think? Is that a reasonable time line?
Dr Bennet-Jenkins—I would really have to take that on notice. I am not quite sure how far along it is in the work order that we have in the department, but I believe it is very close to finalisation.

Answer:

The Preliminary Review Findings (PRF) report for the review of the human health, residues and occupational safety of products containing carbendazim is likely to be released in October-November 2010. The date of finalisation of this review will depend on the extent and nature of the public submissions received in response to publication of the PRF.

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Question: APVMA 04

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Perceived delays in product registration
Hansard Page: Written

Senator COLBECK asked:

There have been a number of concerns lately about the perceived delays in companies having their products – particularly farm chemicals – registered by APVMA.

The Land newspaper reported on the 3rd of May:

> *"The delays are so long that the average time taken to approve a new agricultural crop chemical is now 72 months (six years).*
>
> *Officially, on paper, the industry-funded Australian Pesticides and Veterinary Medicines Authority (APVMA) has a target time to complete its registration approvals in just 13 to 15 months."*

In addition it said:

> *"Last month its Swiss-based manufacturer, Novartis, launched Zolvix in the UK and has recently confirmed its registration across Europe and in Uruguay.*
>
> *"It's ironic that this product was developed basically for the Australian market and was submitted to the Australian regulator first, but we seem to be one of the last countries to get approval for it," Animal Health Australia's chief executive officer, Dr Peter Holdsworth said.*

1. Can you provide some comment on the registration of Zolvix?
2. How long has it taken?
3. What are the delays, if any?
4. Can you provide some comment on the perceived delays in chemicals registration?
5. What is the APVMA's average target time for registrations?
6. How many registrations have not met that target over the past financial year?
7. How do APVMA's target times compare with international agencies?

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (the authority) issued a Public Release Summary (PRS) on 7 June 2010 (see www.apvma.gov.au/registration/assessment/docs/prs_monepantel.pdf) on the evaluation of the new active ingredient, monepantel, in this product. Publication of a Public Release Statement is a requirement under Section 13 of the

Question: APVMA 04 (continued)

Agricultural and Veterinary Chemical Code Act 1994 when considering registration of a new active constituent in a previously registered product. In the public release summary, the authority invites comment from interested stakeholders to say why the product should not be registered. This provides a final opportunity for additional information regarding the risks associated with a product to be submitted before the product is registered.

The legislated public consultation period is 28 days – this period ended on 6 July 2010. Zolvix Monepantel Broad Spectrum Anthelmintic for Sheep was registered, making it available for commercial distribution and use, on 10 August, 2010.

The authority worked positively with the applicant and kept the company informed at all times on progress of its application.

2. The evaluation of this application commenced in July 2008.

3. There were no significant delays within the authority in handling this application. The registration was finalised within the statutory timeframe for this type of application.

4. The authority's legislative framework allows for 'clock on/clock off' provisions where the timeframe clock is 'on and running' when the authority is evaluating the application; and 'off' when the authority is waiting on the applicant to provide additional information. Additional time may also be added to the statutory timeframe where the applicant volunteers additional data for assessment during the evaluation process. It is not uncommon for 50 per cent of the total elapsed time between the initial application and the final approval to be attributed to the time taken to receive additional information from applicants.

   There is no 'average target time for registrations'. Statutory timeframes are set out in the Agricultural and Veterinary Chemicals Code Regulations 1995, and vary depending on the nature of the application.

5. Complex, technical applications have a 5-15 month statutory timeframe, depending on the level of complexity and constitute approximately 20 per cent of the applications finalised each year.

   Non-technical applications (those with a 2-3 month statutory timeframe) constitute about 80 per cent of the applications finalised each year.

Question: APVMA 04 (continued)

6. For the 2009/10 financial year, 2276 applications (including both veterinary medicines and agricultural chemicals) were finalised, with 1910 (or 83.9 per cent) within the statutory timeframe. Three hundred and sixty six applications have not met the statutory timeframe over the past financial year.

   Detailed statistics on registrations are provided in the annual report each year and quarterly on the authority's website.

7. It is difficult to benchmark target timeframes with international agencies as there are considerable differences in how each framework operates. In most OECD countries separate agencies and legislation applies to regulation of veterinary medicines and the regulation of agricultural pesticides. Some agencies have 'clock on/clock off' provisions, some agencies have pre-submission evaluation provisions and in some agencies the timeframes relate only to the risk management component and/or involve two processes with distinct agencies responsible for active constituent approval and product registration. Agency resources for authorisation activities also vary.

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Question: APVMA 05

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Question by Paula Matthewson
Hansard Page: Written

Senator COLBECK asked:

Croplife Australia chief executive officer, Paula Mathewson, recently said

> *"The APVMA has to get back to its core business of evaluating and approving products instead of being pressured to spend more time and money giving government policy advice or responding to claims from activists campaigning against endosulfan."*

1. Is there such a problem with activists taking up the time and resources of APVMA?
2. What is the level of correspondence from those opposed to the use of endosulfan?
3. Have extra resources been put on to deal with this matter?

Answer:

1. The APVMA assesses and responds to all inquiries in accordance with its Service Charter http://www.apvma.gov.au/about/reporting/service_charter.php.

2. The '60 Minutes' television program on 21 March 2010 proposing a link between endosulfan and adverse human health impacts led to the APVMA receiving 161 emails, 25 phone calls and five letters. The announcement on 9 June 2010 by the United States Environmental Protection Agency to proceed to terminate future uses of endosulfan in the United States prompted 15 media enquiries and two emails.

3. No additional resources have been allocated to dealing with general or media inquiries.