

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2015

Agriculture and Water Resources

Question: 25

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Costs in the Federal Court – Abbey Laboratories

Proof Hansard page: 130

Senator BULLOCK asked:

Senator BULLOCK: Can you tell us what the total cost was in defending and settling the action in the Federal Court brought by Abbey Laboratories?

Ms Arthy: I am going to have to take that on notice, because I do not have that information in front of me.

Senator BULLOCK: By all means, take it on notice. Do you want to hazard a guess?

Ms Arthy: No, I could not give a guess.

Answer:

Abbey Laboratories Pty Ltd was the applicant in Federal Court matter NSD402/2015 to which the Australian Pesticides and Veterinary Medicines Authority (APVMA) was the respondent. The total cost for the APVMA in defending the matter was \$13 655.18 including GST. The settlement amount for the applicant's costs was \$23 000.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2015

Agriculture and Water Resources

Question: 26

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Breakdown of registrations under item 6 and item 7

Proof Hansard page: 132

Senator BULLOCK asked:

Senator BULLOCK: In the past I have asked you for a breakdown of registrations from new applicants in six-monthly blocks, as I recall. Now having looked further at this distinction between item 6 and item 7—and I do not imagine that this would be much work because you would have done it in answer to previous questions—could you go back to the January to June 2013 period and the following six-monthly periods and give me a breakdown of those items that have been registered under item 6 and item 7.

Ms Arthy: I will take that on notice. I definitely have not got that here.

Answer:

The number of chemical products assessed under item 6 and item 7 of the Agricultural and Veterinary Chemicals Code Regulations 1995 registered from January 2013 to June 2015 is as follows:

Time period	Number of products registered under item 6			Number products registered under item 7		
	Veterinary	Pesticide	Total	Veterinary	Pesticide	Total
January to June 2013	0	34	34	0	200	200
July to December 2013	0	39	39	12	204	216
January to June 2014	0	20	20	16	97	113
July to December 2014	1	17	18	3	81	84
January to June 2015	3	11	14	26	120	146

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2015

Agriculture and Water Resources

Question: 27

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Letter and survey – proposed relocation

Proof Hansard page: 134-135

Senator BULLOCK and Senator GALLACHER asked:

Senator BULLOCK: One more question on this transfer: have you sought legal advice on this matter?

Ms Arthy: The only legal advice I sought was in the very early stages, about my roles and responsibilities under the act. There has been no further legal advice, to my knowledge.

Senator BULLOCK: So there was not a great deal of cost incurred in that process, I would imagine.

Ms Arthy: No.

Senator BULLOCK: So there was not a great deal of cost incurred in that process, I would imagine.

Ms Arthy: No.

Senator GALLACHER: On Notice, could we have a copy of the letter and the survey that you have mentioned.

Ms Arthy: I will take that on notice.

Answer:

The Australian Pesticides and Veterinary Medicines Authority Chief Executive Officer provided a letter, including the results of a staff survey in relation to possible relocation, to the Minister for Agriculture and Water Resources on 31 July 2015. A copy of the results of the staff survey is attached. The letter contains other material that relates to the deliberative processes of government for a matter that is still under consideration.

Report to the Minister of Agriculture

**Willingness for APVMA Employees to Move to a
Regional Location**

Staff Surveys

July 2015

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Executive Summary

This report considers whether staff at the APVMA would be willing to relocate to a regional location - Armidale, Toowoomba or an alternate regional location near a university with strong agricultural connections.

The APVMA conducted two staff surveys, a preliminary one on 1 June 2015 and the final on 20 July 2015.

The preliminary survey sought to:

- gain staff views on their willingness to relocate to a regional location
- identify the work areas that would be most affected
- gain staff views on which location was considered most favourable, including asking for thoughts on potential other locations
- gain staff views on specific concerns relating to a regional move.

Results from the preliminary survey can be found at Attachment 1.

Between the two surveys the APVMA conducted multiple activities to help staff and their families make an informed choice in relation to a potential relocation.

The final survey sought to:

- gain staff views on their willingness to relocate to a regional location
- identify the disciplines, work areas and APS levels that would be most affected
- gain staff views on which location was considered most favourable — only Armidale or Toowoomba or Armidale/Toowoomba were considered in the final survey
- find out the basis for why staff specifically answered 'yes', 'maybe' or 'no' to a regional move.

1. Foundation of Staff Survey

1.1 Background

Prior to the preliminary survey being conducted, a small working group was created from interested staff via an expression of interest process. An important outcome of the expression of interest process was to provide a good cross section of staff, both across programs and APS levels. Part of the working group's participation brief was to engage with other staff in their respective work areas to make sure the group took into consideration as many staff concerns as possible.

The working group met on three occasions before the release of the preliminary survey. The final survey was a tighter version of the preliminary survey and the working group did not meet prior to the release of the final survey.

1.2 Additional Input

The results of the preliminary survey were distributed to staff via the intranet. The outcome of the preliminary survey shaped some of the activities the APVMA conducted so that staff's concerns could be addressed. A diverse range of APVMA staff were involved in multiple activities to provide staff with additional information prior to the final survey being conducted. These activities were:

- presentations by delegations from Armidale and Toowoomba
- CEO 'cups of tea' small group discussions
- site visits to Armidale and Toowoomba by a small group of staff
- staff workshops.

These activities were held between 12 May 2015 and 20 July 2015 to better inform the staff so they could provide an informed choice/s for the staff surveys.

2. Final Survey Results

2.1 Results

The final survey commenced on 20 July 2015 and closed on 23 July 2015. There was a very high uptake rate for the completion of the survey. A total of 159 people participated in the survey, including permanent, non-ongoing and contract staff. One person partially completed the survey and 158 people completed the survey.

The first question in the final survey was *'Would you be willing to move if the decision was made to relocate the APVMA?'*. Depending on the person's answer to this question they would be directed to a dedicated page for either 'yes', 'maybe' or 'no' answers to complete further questions. To further tease out the 'willingness to move' question there was a second refining question *'What location/s would you consider?'*. Only people that answered 'yes' or 'maybe' had access to this question. The results were:

Table 1 – Willingness to relocate and preferred location

			Armidale or Toowoomba	Armidale only	Toowoomba only
Yes	14	9%	9	1	4
Maybe	35	22%	11	3	20
No	110	69%	NA	NA	NA
TOTAL	159		20	4	24

Note: One "Maybe" did not fully complete the survey. Therefore the total of the final three columns does not equal the total column.

The third refining question was *‘What section at the APVMA do you belong to?’*. People that answered ‘yes’, ‘maybe’ or ‘no’ had access to this question.

Table 2 – Willingness to relocate by discipline and APS Level

	Level	Regulatory Scientists						Grand Total
		Risk Managers Pesticide	Risk Managers Vet Med	Technical Specialists	Subtotal	Legal, Compliance, Licensing	Case Management, Corporate	
Yes	APS 1-6	3	1	1	5	1	4	10
Maybe	SES/EL	0	0	2	2	1	1	4
	APS 1-6	3	2	0	5	1	10	16
No	SES/EL	2	2	3	7	4	7	18
	APS 1-6	7	3	10	20	9	22	51
	SES/EL	7	7	15	29	12	18	59
Total		22	15	31	68	28	62	158

Note: One “Maybe” did not complete this section of the survey, which impacts on the totals compared to Table 1

Depending on the individual's answer to the above questions they would be directed to a dedicated page for 'maybe' or 'no' answers. To further drill down as to why individuals were answering in a specific way an additional refining question '*Why did you answer maybe/no or no' to the question about willingness to relocate?*' was asked. People that answered 'maybe or no' had access to this question only. The top results were:

Table 3 – Why staff answered 'maybe' or 'no'

	Maybe	No
My partner will/may have difficulty in finding work	19 (54%)	82 (75%)
Limited opportunities for future employment progression (myself and/or my family)	21 (60%)	79 (72%)
I have strong ties to the Canberra region	13 (37%)	64 (58%)
I have extended family responsibilities or receive assistance from family/friends in this area	5 (14%)	55 (50%)
I don't want to move children/dependants out of current or intended school	11 (31%)	48 (44%)
I have concerns about the transport links to/from the location	9 (26%)	34 (31%)
I have concerns around the availability of suitably priced real estate (rent or buy)	11 (31%)	21 (19%)
These regions do not support my cultural/community requirements or responsibilities	2 (6%)	18 (16%)
I rely on specialist medical or other support services not available in these regions	2 (6%)	16 (15%)
My family requires a special needs school/program(s)	3 (9%)	5 (5%)
I know nothing about Armidale or Toowoomba	1 (3%)	2 (2%)
Other [large variety]	8 (23%)	31 (28%)

The top results for the question ‘*What support would help?*’ for ‘yes’ and ‘maybe’ answers were:

Table 4 – Assistance/support options

	Yes	Maybe
Assistance with relocation costs	14 (100%)	32 (91%)
Assistance with temporary accommodation	13 (93%)	26 (74%)
Assistance with general relocation logistics	12 (86%)	29 (83%)
Assistance in renting out my property in the Canberra region	8 (57%)	17 (49%)
Assistance with the costs associated with selling my home in the Canberra region	6 (43%)	12 (34%)
Assistance with school placement of children/dependants	3 (21%)	11 (31%)
Other ("assistance with spouse employment", "promotion")	4 (29%)	6 (17%)

The top results for the question ‘*Why would you only consider Armidale and not Toowoomba?*’ for ‘yes’ and ‘maybe’ answers were:

Table 5 – Armidale vs Toowoomba

	Yes	Maybe
I like the size of Armidale compared to Toowoomba	1 (100%)	2 (67%)
I like the geographic location of Armidale compared to Toowoomba	1 (100%)	2 (67%)
I like the education facilities available in Armidale compared to Toowoomba	0 (0%)	2 (67%)
I like the health facilities available in Armidale compared to Toowoomba	0 (0%)	1 (33%)
I like the lifestyle (sporting, cultural etc) choices available in Armidale compared to Toowoomba	0 (0%)	2 (67%)
I like the climate of Armidale compared to Toowoomba	0 (0%)	2 (67%)
I like the job prospects for my spouse/family in Armidale compared to Toowoomba	0 (0%)	1 (33%)
Other – “Closer to family ...”	1 (100%)	0 (0%)

The top results for the question ‘*Why would you only consider Toowoomba and not Armidale?*’ for ‘yes’ and ‘maybe’ answers were:

Table 6 – Toowoomba vs Armidale

	Yes	Maybe
I like the proximity to a capital city of Toowoomba compared to Armidale	4 (100%)	17 (85%)
I like the climate of Toowoomba compared to Armidale	4 (100%)	16 (80%)
I like the geographic location of Toowoomba compared to Armidale	4 (100%)	16 (80%)
I like the size of Toowoomba compared to Armidale	3 (75%)	15 (75%)
I like the job prospects for my spouse/family in Toowoomba compared to Armidale	2 (50%)	15 (75%)
I like the health facilities available in Toowoomba compared to Armidale	2 (50%)	10 (50%)
I like the lifestyle (sporting, cultural etc) choices available in Toowoomba compared to Armidale	3 (75%)	9 (45%)
I like the education facilities available in Toowoomba compared to Armidale	1 (25%)	8 (40%)
Other – “Closer to Sunshine Coast ...”	0 (0%)	1 (5%)

Attachment 1 - Preliminary Survey Results

The preliminary survey commenced on 1 June 2015 and closed on 15 June 2015. There was a very high uptake rate for the completion of the survey. A total of 173 people participated in the survey, including permanent, nonongoing and contract staff. Two people partially completed the survey and 171 people completed the survey.

The first question in the preliminary survey was *'Would you be willing to move if the decision was made to relocate the APVMA?'.* Depending on the person's answer to the above question they would be directed to a dedicated page for either 'yes', 'maybe' or 'no' answers to complete further questions. To further tease out the 'willingness to move' question there was a second refining question *'What section at the APVMA do you belong to?'.* People that answered 'yes', 'maybe', 'no (but would possibly consider)' and 'no' had access to this question. The results were:

Table 1 – Willingness to relocate and disciplines

	Willingness to move	Regulatory Scientists	Legal/ Compliance/ Licencing officers	Non-technical officers
Yes	14 (8%)	5	2	7
Maybe	36 (21%)	19	3	13
No (but Possibly)	21 (12%)	8	7	5
No	102 (59%)	40	17	45
TOTAL	173	72	29	70

The third refining portion of this question was *'What location/s would you consider?'.* Only people that answered 'yes', 'maybe' or 'no (but would possibly consider)' had access to this question. The results were:

Table 2 – Locations

	Option 1 – Armidale	Option 2 – Toowoomba	Option 3 – Other Regional Locations
Yes	6	12	6
Maybe	12	28	13
No (but possibly)	4	14	9
TOTAL	22	54	28

For Option 3 the most popular other regional locations were Wagga Wagga with 13 people, Geelong with 4 people, Wollongong and Orange with 3 people each.

The second key element to the survey was for the APVMA to gauge staff views on specific concerns relating to a regional move and how the APVMA would be able to assist staff in addressing this information deficit.

The top 5 results for the question ‘*What further information would you like to know?*’ for ‘yes’, ‘maybe’ and ‘no’ answers the results were:

Table 3 – Further information

	Yes	Maybe	No
Personal job security	13 (93%)	n/a	13 (62%)
Real estate options (rent or buy)	10 (71%)	n/a	6 (29%)
Spouse employment opportunities	9 (64%)	23 (64%)	15 (71%)
Availability of support services (e.g. specialist medical, aged care facilities)	6 (43%)	12 (33%)	7 (33%)
Other	5 (36%)	0 (0%)	0 (0%)

The top results for the question ‘*What support would help?*’ for ‘yes’, ‘maybe’ and ‘no (but would possibly consider)’ answers the results were:

Table 4 – Support that would help

	Yes	Maybe	No (possibly)
Assistance with relocation costs	14 (100%)	32 (89%)	17 (81%)
Assistance with temporary accommodation	13 (93%)	26 (72%)	15 (71%)
Assistance with general relocation logistics	12 (86%)	19 (53%)	16 (76%)
Assistance in renting out my property in the Canberra region	8 (57%)	14 (39%)	11 (52%)
Assistance with the costs associated with selling my home in the Canberra region	3 (21%)	n/a	14 (67%)
Assistance with school placement of children/dependants	3 (21%)	n/a	n/a

Depending on the individual’s answer to the above questions they would be directed to a dedicated page for ‘maybe’ or ‘no’ answers. To further tease out why individuals were answering in a specific way an additional refining question ‘*Why did you answer ‘maybe’ or ‘no’ to the question about willingness to relocate?*’ was used. People that answered ‘maybe’ or ‘no’ had access to this question only. The results were:

Table 5 – Unwillingness to relocate

	Maybe	No
Limited opportunities for future employment progression (myself and/or my family)	23 (64%)	91 (74%)
My partner would not be able to find an equivalent job	17 (47%)	89 (72%)
I don't want to move children/dependants out of current or intended school	13 (36%)	53 (43%)
I have strong ties to the Canberra region	15 (42%)	72 (59%)
I have concerns about the transport links to/from the location	14 (39%)	37 (30%)
Availability of suitably priced real estate (rent or buy)	13 (36%)	n/a
I have extended family responsibilities or receive assistance from family/friends in this area	9 (25%)	49 (40%)
I know nothing about Armidale or Toowoomba	7 (17%)	15 (12%)
These regions do not support my cultural/community requirements or responsibilities	n/a	21 (17%)
I rely on specialist medical or other support services not available in regional Australia	n/a	24 (20%)
I would not sell/leave my current home	n/a	58 (47%)

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2015

Agriculture and Water Resources

Question: 28

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: New data sets

Proof Hansard page: 135

Senator SIEWERT asked:

Senator SIEWERT: You mentioned new data sets since the last assessment. What are they likely to be?

Dr Bhula: I cannot give you specifically what the new data sets are. We can take that question on notice. What we are looking at is other information that has been published in the public domain that we may not have looked at as part of our previous regulatory assessments.

Senator SIEWERT: That is not part of the IARC process?

Dr Bhula: The epidemiological studies that the IARC looked at as part of their process.

Senator SIEWERT: If you could take that on notice that would be great. I have one other question that, I must admit, may provoke another. The \$20.4 million to further streamline the approval of agricultural and vet chemicals—I understand that the implementing agency is the Sustainable Agriculture and Fisheries Division. I just wonder how you relate to that process.

Ms Arthy: We have not been formally involved in that process, so the questions will have to go to the department.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has requested the Department of Health's Office of Chemical Safety to review the 264 references cited in the International Agency for Research on Cancer (IARC) Monograph on glyphosate. These references are all available in the public domain and cover a range of subject matter including human epidemiological studies, animal cancer studies, genotoxicity assays and more general experimental investigations. The IARC assessment did not consider unpublished proprietary studies available to pesticide regulators. Additionally, the APVMA will consider assessment reports by the European Food Safety Authority (EFSA) and United States Environmental Protection Agency (US EPA) that are expected to be published in the coming months.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2015

Agriculture and Water Resources

Question: 29

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Proprietary rights

Proof Hansard page: 137

Senator BULLOCK asked:

Senator BULLOCK: Fair enough. I am sure it is keenly anticipated. I just want to go to the proprietary rights to the data legislation. If that legislation was withdrawn, could we expect to see a large number of generic applications received by the APVMA from multinationals rather than Australian companies?

Ms Arthy: The proprietary rights? I am not aware of that. We would have to take that one on notice, because I do not know.

Answer:

The Australian Pesticides and Veterinary Medicines Authority is not aware of any legislative proposals relating to withdrawal of proprietary rights.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2015

Agriculture and Water Resources

Question: 30

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: APVMA relocation

Proof Hansard page: Written

Senator STERLE asked:

1. Provide update on the status of the Minister's determination to relocate APVMA.
2. Has the Minister sought additional information regarding the relocations
3. Has the Minister wrote to APVMA seeking a decision by the end of June 2015 - has the Minister been provided with answers
4. If no, has the Minister written to the APVMA seeking their final answer
5. Does the Minister have the power to forcibly move APVMA out of Canberra if they choose not to move
6. Has the APVMA sought legal advice regarding the Minister's request for relocation
7. What has been the cost associated with seeking legal advice and the time spent by the APVMA in dealing with the matter
8. Has the Minister sought to meet with APVMA in person to discuss the relocation
9. Can you update the committee on the Hendra Virus.
10. Is it true that since the introduction of 'Proprietary rights to Data' was introduced the generic registration submissions have fallen by over 50%.
11. Is it true that APVMA because of systems implementation issues and staff problems has limited the number of submissions from the largest registration submission operations from 32 submissions to 2 per month
12. If the Proprietary rights to Data legislation was withdrawn we could expect to see a large number generic applications received by the APVMA from both the Multinational and smaller Australian based manufactures. Providing the APVMA can access the original data package we could see these applications rise by 50-60 per cent. Export dollars would increase by over 50% in some cases double in eighteen months.
13. With less and less products being brought to market from original research companies the future of both the local Australian manufactures and now in some cases even the Multinationals is dependent on the legislation being removed

Question: 30 (continued)

14. If Australia is to become one of the major food producers in the western world then the industry needs the APVMA to be active in helping registrant's gain registration of their products in a safe and efficient way.

Answer:

1. The Department of Agriculture and Water Resources has advised that the government is considering advice from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on its potential relocation to regional Australia.
2. Yes
3. Yes
4. Not applicable
5. The Department of Agriculture and Water Resources has advised that, as this is a legal question, it is not appropriate for the department to disclose legal advice to the committee.
6. Yes
7. Staff consultation costs = \$14 472. Legal advice costs = \$2 278.32.
8. Yes
9. On 4 August 2015 the APVMA registered a Hendra virus vaccine. Details of registered chemical products are available on the APVMA website at <http://apvma.gov.au/node/10831>.
10. The APVMA is not aware of any legislative proposals relating to proprietary rights. For details on product registrations for applications assessed under items 6 and 7 of the *Agricultural and Veterinary Chemicals Code Regulations 1995*, refer to the response to Question on Notice APVMA02 from the Rural and Regional Affairs and Transport Legislation Committee Supplementary Budget Estimates hearing on 20 October 2015.
11. No
12. The number of applications received by the APVMA for registration of agricultural and veterinary (agvet) chemicals is influenced by a range of issues. The legislative framework for regulation of agricultural and veterinary chemicals is one factor applicants consider. Other factors include seasonality, market opportunities, climate and trends in agricultural and manufacturing industries.

Question: 30 (continued)

13. Refer to question 12

14. The APVMA assesses product registration applications to ensure the proposed use is safe for humans, animals and the environment, effective and will not adversely impact trade. The APVMA focuses assessment based on the level of risk associated with the proposed use of the product. The APVMA is currently working on a number of major projects to make the registration process more efficient for applicants. These focus on applying lower regulatory intervention for registration of products with lower regulatory risk; increased use of international assessments, adoption of relevant international guidelines and standards and improved arrangements for sharing of information; improved systems and processes to support end-to-end registration of products and quality decision making; and enhancing applicant experience through improved guidance material and service delivery.