

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 56

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Relationship with ANU

Proof Hansard page: 64

Senator RICE asked:

Senator RICE: Being based in Canberra, what has your relationship been like with ANU? Have you done work with them?

Ms Arthy: We probably have, but I would have to take that on notice in terms of what scientific work we have done. We do more work with CSIRO because they have more science that is relevant to us.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) works with consultants including academics from universities, depending on the nature of the expertise required for the work being undertaken.

As an example, the APVMA contracted the Centre of Excellence for Biosecurity Risk Analysis at the University of Melbourne to develop a risk assessment framework where the level of regulatory intervention is proportional to the risks associated with the application or chemical product.

The APVMA has no formal working relationship with the Australian National University.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 57

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: CSIRO

Proof Hansard page: 64-65

Senator RICE asked:

Senator RICE: Where is the CSIRO's expertise relevant to you? Where is that based?

Ms Arthy: That I do not know. I shall just check. I have just got advice that some of the expertise is here in Canberra, but we deal with such a wide variety of issues that we tend to work with agencies across Australia.

Answer:

The Australian Pesticides and Veterinary Medicines Authority utilises scientific expertise in relation to emerging technologies as required. In this regard, the CSIRO provides expertise in interference RNA (Perth, Western Australia location) and Gene Drive Technologies (Australian Animal Health Laboratories, Geelong Victoria location).

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Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 58

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Application timeframes

Proof Hansard page: 68

Senator CAROL BROWN asked:

Senator CAROL BROWN: Ms Arthy, what is the statutory time frame in which the APVMA must process applications?

Ms Arthy: There are actually 29 items and each one has a different time frame. To make things even more complicated, a couple of those items are known as modular, which means it depends on how much analysis we do. So there is not one answer for you, but it is in schedule 6 of our regulations, which we can provide you with.

Answer:

The statutory timeframes for assessment of applications under the Agricultural and Veterinary Chemicals Code 1994 are set out in Part 2 of Schedule 6 of the Agricultural and Veterinary Chemical Code Regulations 1995 which can be accessed through the Federal Register of Legislative Instruments <https://www.legislation.gov.au/Details/F2016C00660> and provides:

Table of fees and assessment periods					
Item	Description of application	Assessment period (months)	Extended Assessment period (months)	Maximum pre application assistance rebate (\$)	Fee from 1 January 2015 (\$)
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 (other than a timeshift application)	18	25	1 400	96 135
2	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 less than full assessment of the active constituent	The modular assessment period	One and one third of the modular assessment period, rounded up to the	1 400	The modular assessment fee

	and chemical product (other than a timeshift application)		nearest whole month, plus 1 month		
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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 (other than a timeshift application), if: (a) there is no registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required	18	25	1 050	64 620
4	Application (other than a timeshift application) for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is a registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required; and (c) there are no relevant maximum residue limits; and (d) poison schedule classification is required	18	25	1 050	36 675
5	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is similar to a registered chemical product; and (b) chemistry and manufacture, efficacy or target species safety data is the only data required to demonstrate the similarity of the chemical product to the registered chemical product	8	12	700	4 870
6	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are required	8	12	700	4 290

7	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are not required	3	5	350	1 755
8	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is the same as a registered chemical product; and (b) the chemical product is to be registered with a different name	3	5	350	1 655
9	Application for registration of a listed chemical product and approval of a product label where the product and label comply with an established standard that has been approved in accordance with section 8U of the Code	2	4	350	1 595
10	Application for registration of a chemical product containing an approved active constituent (or an active constituent for which the APVMA has received an application for approval) and approval of the product label for all situations other than those described in items 3 to 9	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	350	The modular assessment fee
10A	Application for approval of a label for containers for a registered chemical product	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	350	The modular assessment fee
Applications to vary a registration or label approval					
11	Application to vary particulars or conditions of registration or label approval where a full assessment of the chemical product is required	10	15	1 050	28 610

12	Application to vary particulars or conditions of registration or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required	3	5	350	1 170
13	Application to vary particulars or conditions of registration or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA	3	5	Nil	Nil
13A	Application to vary a relevant particular of an approval or registration where the variation of the relevant particular is a prescribed variation under section 26B of the Code	1	Not applicable	Nil	175
14	Application to vary particulars or conditions of registration or label approval if the application is not of a kind described in any of items 11 to 13A	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	350	The modular assessment fee
Applications for approval of an active constituent					
15	Application for approval of an active constituent requiring a full assessment (other than a timeshift application)	14	20	1 400	30 550
16	Application for approval of an active constituent requiring less than full assessment but requiring a toxicological assessment	9	13	700	18 805
17	Application for approval of an active constituent requiring less than full assessment but not requiring a toxicological assessment	7	11	700	3 155
Applications for variation to an approved active constituent					
18	Application to vary particulars or conditions of an approved active constituent	7	11	700	2 465
Applications for permits					
19	Application for a permit, or extension of 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, where no data of a technical nature is required	3	5	350	350

20	Application for a permit, or extension of a permit, where a previous assessment remains valid and no data of a technical nature is required	3	5	350	350
21	Application for a permit, or extension of a permit, where the proposed use is a minor use	The modular assessment period	The modular assessment period, plus 6 months (unless the APVMA and the applicant agree to a shorter period)	350	350
22	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an emergency use	Not applicable— (see sub-regulation 76(4))	Not applicable	Nil (see paragraph 70 (8)(b))	Nil (see paragraph 70(8)(b))
23	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the application is not of a kind described in any of items 19 to 22	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	350	The modular assessment fee
24	Application made under section 10 of the Code (other than those of the kinds described in any of items 1 to 10, 15, 16 or 17) requiring assessment of a technical nature	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	350	The modular assessment fee
25	Application for a technical assessment made under regulation 8AS	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee, plus GST
27	Timeshift application	The modular assessment period	Not applicable	1400	The modular assessment fee
28	Application made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination	The modular assessment period	One and one third of the modular assessment	Nil	The modular assessment fee

			period, rounded up to the nearest whole month, plus 1 month		
29	Application made under regulation 19AEB to make an interchangeable constituent determination	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee

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Agriculture and Water Resources

Question 59

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Applications timeframe

Proof Hansard page: 68

Senator CAROL BROWN asked:

Senator CAROL BROWN: On that 83 per cent, are the applications on the less complex end? Can you give me some more information about that?

Ms Arthy: We can provide that information. We are about to publish the September quarter figures.

Answer:

The Australian Pesticides and Veterinary Medicines Authority publishes performance statistics for:

- a. major assessments, which have assessment periods over three months and require one or more technical assessments.
- b. non-technical assessments, which have assessment periods of three months or less.

For the period July to September 2016, timeframe performance for major and non-technical assessments was:

	Major Assessments	Non-technical assessments
Pesticides	64 per cent	95 per cent
Veterinary medicines	68 per cent	99 per cent
Total	66 per cent	97 per cent

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Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 60

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

In July 2014 (<http://apvma.gov.au/node/97>), the APVMA indicated that it was in the process of developing detailed guidelines to address issues of nanomaterials being used in agricultural products.

- a) Have detailed guidelines been developed?
- b) If no to a) are they being developed?
- c) If no to b) why not?
- d) If no to a), and advice (questions 3-5) has been provided to companies, on what basis was the advice provided if no guidelines were in place?
- e) If yes to a), when are they expected to be finalised?

Answer:

- a) No
- b) Guidelines are being developed by the Organisation for Economic Co-operation and Development (OECD) and the International Union of Pure and Applied Chemistry (IUPAC), both of which the Australian Pesticides and Veterinary Medicines Authority (APVMA) participates in.
- c) Not applicable.
- d) General advice on nanomaterials has been provided using existing APVMA guidelines for conventional products where applicable and guidance material from OECD and IUPAC.
- e) Not applicable.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 61

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

In September 2015, the APVMA noted that “relatively few applications have been commercialised in these sectors globally and only one product has been registered in Australia.” (http://apvma.gov.au/sites/default/files/publication/15626-nanotechnologies-pesticides-veterinary-medicines_regulatory-considerations_july2015.pdf., p. 20

How many applications have been received by the APVMA since that time? (please provide details of the applications)

Answer:

The Australian Pesticides and Veterinary Medicines Authority is not aware of receiving any applications for products containing nanomaterials since September 2015.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 62

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Glyphosate

Proof Hansard page: Written

Senator RICE asked:

In response to Senate Estimate question 3000, the APVMA noted that “The IARC report did not include an assessment of the risk of the formulated products when used as directed.” Does the APVMA have any data on the level of compliance with glyphosate directions by:

- a) Primary producers
- b) Local councils
- c) Individuals

Answer:

No. The Australian Pesticides and Veterinary Medicines Authority’s legislative powers extend up to the point of retail sale - any issues of non-compliance with directions for use of glyphosate products are a matter for state control-of-use authorities.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 63

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Glyphosate

Proof Hansard page: Written

Senator RICE asked:

When were the current use directions for glyphosate put in place?

Answer:

Directions for use are set at the time of each individual product registration based on the comprehensive risk assessment undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and reflecting the use patterns approved for each product.

Details of registered products are available on the APVMA website (apvma.gov.au) which show the registration date and approved directions for use for all registered products.

A number of glyphosate products were originally registered under state and territory regulatory frameworks and transitioned to the National Registration Scheme for Agricultural and Veterinary Chemicals from 1994 to be managed by the APVMA.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 64

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Glyphosate

Proof Hansard page: Written

Senator RICE asked:

Has the level of human and environmental exposure to glyphosate increased since that time as a result of increased usage and higher dosages?

Answer:

Available evidence indicates that human and environmental exposure to glyphosate is not significant. The National Residue Survey undertaken by the Department of Agriculture and Water Resources rarely finds glyphosate above the legally permissible level (the Maximum Residue Limit – MRL). The most recent dietary survey conducted by Food Standards Australia New Zealand indicated that public exposure to glyphosate residues in food is well below the safe health limits. Glyphosate is short-lived in the environment and does not tend to be detected in soil or water. The Australian Pesticides and Veterinary Medicines Authority is not aware of any environmental monitoring data to indicate that environmental exposure has increased.

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Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 65

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Glyphosate

Proof Hansard page: Written

Senator RICE asked:

Can the APVMA provide a list of water supplies that have been tested for and have found to have traces of glyphosate in them?

Answer:

The Australian Pesticides and Veterinary Medicines Authority does not undertake environmental testing or maintain a list of water supplies that have been tested for glyphosate. State catchment authorities and water bodies are responsible for monitoring the quality of the water supply, including drinking water, for the presence of microbiological and chemical agents.

The National Health and Medical Research Council maintains the Australian Drinking Water Guidelines, which indicates that glyphosate is generally not reported in analysis of Australian waters and is unlikely to be found in drinking water at levels that may cause health concerns.

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Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 66

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Glyphosate

Proof Hansard page: Written

Senator RICE asked:

Is there a federal body that collates pesticide pollution of water supplies gathered from federal testing and state testing?

Answer:

No.

Rural and Regional Affairs and Transport Legislation Committee

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Agriculture and Water Resources

Question: 67

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Relocation

Proof Hansard page: Written

Senator XENOPHON asked:

Has APVMA surveyed staff as to how many will shift to Armidale?

- a) If so, by what category of management/staff type, what percentage of staff will move?
- b) If not, why not?

Answer:

Yes, the Australian Pesticides and Veterinary Medicines Authority surveyed staff in July 2015 about their willingness to move to Armidale and Toowoomba. The survey was completed by 158 staff, with 14 staff indicating their willingness to move to Armidale and/or Toowoomba.

The survey did not provide percentages of staff by category willing to move only to Armidale. However, the percentages of staff by category willing to move to Armidale and/or Toowoomba is in the table below.

	Risk Managers Pesticide	Risk Managers Veterinary Medicines	Technical specialists	Legal, Compliance, Licensing	Case Management, Corporate	Total
APS 1-6 staff willing to relocate	3 (14%)	1 (7%)	1 (3%)	1 (4%)	4 (6%)	10
SES/EL staff willing to relocate	0	0	2 (6%)	1 (4%)	1 (2%)	4
Total survey respondents	22	15	31	28	62	158

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Agriculture and Water Resources

Question: 68

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Florentine Gold

Proof Hansard page: Written

Senator XENOPHON asked:

With respect to the small South Australian company, Florentine Gold, who have been advised that their insect repellent cannot be advertised due to ss. 75 and 78 of the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) and s. 88 of the Agvet Code:

Noting their product is said to be made up of 100% natural content and contains no chemicals, how does it fall within the bounds of Act?

Answer:

The Florentine Gold is a personal insect repellent. Personal insect repellents are declared to be agricultural chemical products under Schedule 3, Part 2 of the *Agricultural and Veterinary Chemicals Code Regulations 1995*, and therefore require Australian Pesticides and Veterinary Medicines Authority (APVMA) registration before they can be sold or advertised.

Possession with intent to supply (section.75), the supply (section.78) and advertising (section.88) of agricultural chemical products that are not registered are possible contraventions of the *Agricultural and Veterinary Chemicals Code Act 1994*.

A number of personal insect repellent products containing naturally derived chemicals such as citronella oil, eucalyptus oil and melaleuca oil have been registered by the APVMA.

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Agriculture and Water Resources

Question: 69

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

How many of those companies were advised that they should apply for approval?

Please table the advice provided to each of these companies.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is aware of contact from three companies and organisations regarding agricultural and/or veterinary chemical products that contain nanomaterials. General advice about the regulatory environment and the APVMA application process was provided to these companies and organisations.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture and Water Resources

Question: 70

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Average length of service by staff

Proof Hansard page: 47

Senator BACK asked:

Senator BACK: What number of FTE staff do you have now?

Ms Arthy: At the moment we have 190 FTE.

Senator BACK: Are they represented by 190 people, or are they—

Ms Arthy: The head count is 195 people.

Senator BACK: And length of service: what is the average length of service? Do you have that figure, or can you take it on notice?

Ms Arthy: I will have to take that on notice.

Answer:

The average length of service for all Australian Pesticides and Veterinary Medicines Authority (APVMA) employees as at 18 October 2016 was 5.8 years. The average length of services for all on-going APVMA employees as at 18 October 2016 was 6.5 years.

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Agriculture and Water Resources

Question: 71

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Face to face meetings

Proof Hansard page: 66

Senator RICE asked:

Senator RICE: Do you have regular meetings with Canberra bureaucrats and ministers and ministers' staff?

Ms Arthy: Certainly we meet with the department. We would meet weekly on several issues. We also work very closely with our regulatory partners—counterparts like the TGA, the industrial chemicals regulator and Food Standards. We do work fairly closely with them as well.

Senator RICE: How many face-to-face meetings in Canberra would staff currently have?

Ms Arthy: I would have to take that on notice if you wanted an exact figure, but I would say we would have meetings nearly daily on a few of these things.

Senator RICE: How many staff would have meetings daily in Canberra?

Ms Arthy: I do not know. I would be plucking a number out of the air. I would have to take that on notice if you want something more accurate.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) surveyed SES and EL2 staff on the total number of face-to-face meetings held with external stakeholders in Canberra (at the APVMA or off-site) between 1 July to 30 September 2016. The APVMA also reviewed the number of face-to-face meetings held under the pre-application assistance program.

Based on this, on average, the APVMA had 109 face-to-face meetings with external stakeholders per month in Canberra (at the APVMA or off-site) between 1 July to 30 September 2016.

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Question: 72

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

According to the APVMA website until March 2014, “Assessment of agricultural and veterinary chemicals and chemical products currently registered in Australia has not identified any to contain engineered nanomaterials.”

That claim has now been removed.

Has the APVMA identified any agricultural or veterinary chemicals in use in Australia that contain nanomaterials?

- a) If yes, please identify those chemicals.
- b) If no, please indicate what steps have been taken between March 2014 and the present to determine whether any agricultural or veterinary chemicals are in use in Australia.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is aware of one veterinary chemicals product and no agricultural chemical products registered for use by the APVMA in Australia that contain nanomaterials.

- a) The registered product is Propoclear (product Number. 62710).
- b) Not applicable.

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Agriculture and Water Resources

Question: 73

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

In reply to Senate Question 882 asked on 26th September 2014, the Minister for Agriculture indicated that - in relation to products that contain nanomaterials - “applicants are advised to contact the APVMA to discuss their specific requirements before making an application.”

Does this mean that the APVMA no longer maintains that “existing substances reformulated at the nanoscale would be considered as new substances” as the APVMA indicated in its 2008 publication The APVMA and Nanotechnology?

Answer:

The Australian Pesticides and Veterinary Medicines Authority maintains that existing substances reformulated at the nanoscale would be considered as new substances.

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Agriculture and Water Resources

Question: 74

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

How many companies have contacted the APVMA regarding:

- a) agricultural products containing nanomaterials?
- b) veterinary products containing nanomaterials?

Answer:

The Australian Pesticides and Veterinary Medicines Authority is aware of contact from three companies and organisations regarding agricultural and/or veterinary chemical products that contain nanomaterials, two for agricultural products and one for a veterinary medicine product.

Rural and Regional Affairs and Transport Legislation Committee

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Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 75

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

How many companies were advised that no application was necessary?

a) Please table advice provided to each of these companies.

Answer:

The Australian Pesticides and Veterinary Medicines Authority is not aware of any companies being advised that no registration application is necessary for products containing nanomaterials.

Rural and Regional Affairs and Transport Legislation Committee

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Supplementary Budget Estimates October 2016

Agriculture and Water Resources

Question: 76

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nanomaterials

Proof Hansard page: Written

Senator RICE asked:

How many of these products are now commercially available in Australia?

a) Please identify the products.

Answer:

The Australian Pesticides and Veterinary Medicines Authority is aware of one agricultural or veterinary chemicals in use in Australia that contain nanomaterials.

a) Propoclear, Product No. 62710