Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 23

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Availability of Ag Vet chemicals
Proof Hansard Page: 117 (23/05/11)

Senator Back asked:

Senator BACK: It is my understanding that at the moment one company has a product registered for use. Is that correct?
Dr Bennet-Jenkins: Yes. There are several products registered for use but primarily in crop protection.
Senator BACK: Is it still just the one company that has this product available on the market, to your knowledge?
Dr Bennet-Jenkins: I think there is more than one product available, but there are not many suppliers that can supply the product. We can get you a list of the products that are available on notice, if you would like.
Senator BACK: Yes, thank you. (cont.)

Answer:

There are three companies that hold registrations for the mouse bait product containing zinc phosphide. A list of the approved products is provided for information in Attachment 1.

[Attachment]

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 23 (continued)

ATTACHMENT 1 : Public Chemical Registration Information System PUBCRIS List of Approvals and Registrations for Zinc Phosphide

Public Chemical Registration Information System - PUBCRIS

Export List **New Search**

Active Constituent Contains ZINC PHOSPHIDE

7 Products Found

Product List

Approval No	Product Type	Product Name	Active(s)	Details
44062	ACTIVE CONSTITUENT	ZINC PHOSPHIDE	ZINC PHOSPHIDE	Single Page
48824	ACTIVE CONSTITUENT	ZINC PHOSPHIDE	ZINC PHOSPHIDE	Single Page
49431	ACTIVE CONSTITUENT	ZINC PHOSPHIDE	ZINC PHOSPHIDE	Single Page
50532	VERTEBRATE POISON	MOUSEOFF ZINC PHOSPHIDE BAIT	ZINC PHOSPHIDE	Single Page View Label
58041	VERTEBRATE POISON	RATTOFF ZINC PHOSPHIDE BAIT SACHETS	ZINC PHOSPHIDE	Single Page View Label
59797	VERTEBRATE POISON	SUREFIRE ZINC PHOSPHIDE MOUSE BAIT	ZINC PHOSPHIDE	Single Page View Label
60832	VERTEBRATE POISON	ZP MOUSE ZINC PHOSPHIDE BAIT	ZINC PHOSPHIDE	Single Page View Label

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 24

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Use of trichlorfrom (reference to a letter)
Proof Hansard Page: 119 (23/05/2011)

Senator Back asked:

Senator BACK: I saw some correspondence when I was looking at this of a letter that had come from the department to the minister in which the writer was indicating a low- or no-volatility risk associated with the use of trichlorfon and the unlikely event of it breaking down into dichlorvos. Is that something you still maintain to be the circumstance?
Dr Bennet-Jenkins: I might have to take that particular question on notice, because I am not aware of that letter. It is probably a letter that has come from the department rather than the authority. Maybe it is best if we can take that on notice, because it is a letter that has come from the department.
Mr Glyde: The minister has received some correspondence in relation to this matter which we have had our chief scientist investigate. We are in the process of drafting some correspondence for the minister to consider.

Answer:

See answers to 37 (APD/APVMA) Budget Estimates May 2011.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 25

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Staff turnover rate
Proof Hansard Page: 120 (23/05/2011)

Senator BACK asked:

Senator BACK: What is the level of staff turnover in the agency? Is it increasing or decreasing?
Dr Bennet-Jenkins: Staff turnover, I believe, is around 9 to 10 per cent for the year to date—or the annual separation rate; it might be an annualised figure. We could give you a more specific figure, but it is about that.
Senator BACK: Is that consistent with the recent past and is that figure consistent with the overall department?
Mr Glyde: I would have to take that on notice in terms of our turnover rate. It varies from year to year.
Dr Bennet-Jenkins: It is within our target. Yes, 9.5 per cent is the total separation rate.

Answer:

As at 30 April 2011 the annual APVMA separation rate was 9.5 per cent.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 26

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: New applications that come before APVMA
Proof Hansard Page: 120-121 (23/05/2011)

Senator Back asked:

Senator BACK: Am I right in my question that your New Zealand equivalent does in fact have some process whereby an applicant can pay a fee for an expedited assessment? Are you familiar with that?
Dr Bennet-Jenkins: I would have to take that on notice to really verify that I am giving you the correct information on that question.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) equivalent in New Zealand, the Agricultural Compounds and Veterinary Medicines Group (ACVM) in the New Zealand Food Safety Authority was consulted in the preparation of this response.

The ACVM does not have a process in place where an applicant can pay additional fees for an expedited assessment, ie a ‘fast-track’.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 27

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Honey bees – chemicals used
Proof Hansard Page: 121 (23/05/2011)

Senator Milne asked:

Senator MILNE: So you are satisfied that those chemicals do not pose a risk to bees in Australia?
Dr Bennet-Jenkins: Not if the products are used in accordance with the label instructions and they are not sprayed when bees are foraging. There are very extensive label instructions in terms of how to mitigate the risks to bees.
Senator MILNE: When were they approved?
Dr Bennet-Jenkins: I would have to take that on notice. I do not know the exact year when the first approval was made or when the first approvals related to uses in crops where bees were a particular concern.

Answer:

The first imidacloprid products were registered under the state scheme in Victoria in 1993 . Subsequent registrations were in South Australia and Tasmania in 1995 and Victoria and Queensland in 1996. Imidacloprid as an active constituent was first approved by the then National Registration Authority in 1996 and the first products were registered in 1998.

Clothianidin, was first approved as an active constituent in 2003 and products were registered in 2007.

This information is available on the APVMA website at:
services.apvma.gov.au/PubcrisWebClient/welcome.do

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ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 28

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Testing list of chemicals that FSANZ gives to AQIS
Proof Hansard Page: 124 (23/05/2011)

Senator Colbeck asked:

Senator COLBECK: Dr Bennet-Jenkins has not actually strayed into that, and I have tried not to ask questions directly about it. I am trying to get some sense of the interaction between APVMA, which is an agency with obvious expertise in that area, and FSANZ, which actually does do that work. That is what I am trying to get to. Perhaps my next question might take it a bit further. We have had some conversations with both FSANZ and AQIS about the testing list of chemicals that FSANZ gives to AQIS to test products at the border. My question is: does FSANZ seek advice from the APVMA in respect of the make-up of that list?
Dr Bennet-Jenkins: I would have to take that on notice. I am not aware that it does.
Senator COLBECK: I am just not sure that I am completely satisfied as to where we are at with that, but it is something that we need to continue to pursue. I will leave it at that for the moment.

Answer:

No.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 29

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Spray application pesticides
Proof Hansard Page: Written

Senator Heffernan asked:

Spray application pesticides, chemical health issues and exposure to dangerous pesticides by members of the public.

1. Why does the APVMA allow application of pesticides to crops for which the APVMA has no data on the potential for spray drift- e.g. avocadoes, macadamias? AGDRIFT has no data for these crops, and even the scientist who created AgDrift (Prof Andrew Hewitt) is unwilling to speculate as to whether AgDrift could be predictive for crops other than those which were actually tested, under the climatic conditions of the USA under which they were tested.
2. Why does the APVMA not require registrants to supply data on spray drift for application to all specific individual crops by all permitted methods, such as air blasting, as was required by the US EPA prior to the submission of the data generated by the chemical companies in the Spray Drift Taskforce AgDrift model project?
3. Does the APVMA consider that a neighbour to an orchard, with a home under 100m from the edge of the orchard, may suffer inadvertent exposures, of the quantum of occupational inhalational and dermal exposures, particularly from products which volatise and continue to be available for off-site movement for days after application, such as trichlorfon?
4. Is APVMA aware of the several epidemiological and peer reviewed studies linking the impact of pre-natal exposure to organophosphate pesticides and their children's diminished IQ?
5. If the APVMA are aware of this research, what action do they propose to take regarding pre-natal exposure to organophosphate pesticides? Under real world changing wind conditions are current label conditions sufficiently protective to prevent exposure to these organophosphates?
6. How do current labelling and notification requirements permit neighbours to be protected from such exposure risk?
7. Does the APVMA consider that a neighbour to an orchard, with a home under 100m from the edge of the orchard, may suffer inadvertent exposures, of the quantum of occupational inhalational and dermal exposures, particularly from products which volatise and continue to be available for off-site movement for days after application, such as trichlorfon?
8. Is the APVMA aware of the epidemiological paper demonstrating enhanced risk of Non-Hodgkins Lymphoma in persons occupationally exposed to pesticides?
9. What legislative changes or resourcing changes would assist the APVMA in completing full pesticide reviews in under 12 months from the time of initiation?

Question: 29 (continued)

10. When will the APVMA conduct toxicological evaluation of excipient chemicals used in pesticide products, especially as these chemicals have been banned in other countries for their adverse affects e.g. nonylphenol surfactants, and impurities such as dioxins?
11. When will the APMVA commence toxicological evaluation of both active ingredients and other agents (such as surfactants) that are used in pesticides, herbicides and other agricultural chemicals, in order to characterise endocrine disrupting potential according to the US EPA definition of endocrine disrupting compounds as being 'exogenous agent(s) that interfere with synthesis, secretion, transport, metabolism, binding action, or elimination of natural blood-borne hormones that are present in the body and are responsible for homeostasis, reproduction, and developmental process'?
12. When will the APVMA undertake full life-cycle toxicological testing with the best available scientific evidence (including endocrine disruption and immune function modulation using in vitro models) for pesticide product mixtures (including impurities) and those frequently applied as mixtures, especially those which have been detected in waterways draining locations of agrichemical application?
13. When will the APVMA ensure markers are used in pesticides by manufacturers, retailers, land owners and therefore 'applicators', to enable pollution to be traced to the source?
14. When will the APVMA undertake monitoring of off-site pesticide movement, to determine if its desk top risk assessments, which are largely based on registrants data, have under Australian conditions been sufficiently protective, to ensure no exceedance of ANZECC water quality guidelines, during the full range of climatic conditions?

Answer:

1. Dr Andrew Hewitt is an eminent spray drift expert, but he did not create the AgDRIFT model.

   For ground applications of agricultural chemicals, the Australian Pesticides and Veterinary Medicines Authority (APVMA) uses the AgDRIFT model to assess spray drift risks for all new chemicals and to assess spray drift risks in its program of spray drift reviews of existing chemicals. The model is based on a very large and comprehensive data set which the APVMA has determined to closely match Australian climatic conditions and agricultural production systems including avocado and macadamia production.

2. The APVMA applies rigorous assessments to all applications, including assessment of spray drift risk where required. The APVMA approach to spray drift risk is to use the AgDRIFT model and apply standard scenarios relevant to Australian conditions (developed by the APVMA). With respect to ground

Question: 29 (continued)

application, the APVMA uses AgDRIFT with input parameters that allow risk to be considered at the higher end of what would commonly be expected from in field use. Depending upon the nature of the product and its use, some parameters are assessed at values ranging between typical field conditions and higher risk conditions that might be likely to occur. The APVMA may require, or registrants may choose to provide, data for specific situations to allow a more refined risk assessment to be conducted. Specific data may allow less stringent risk mitigation measures than those derived from modelling alone.

3. The likelihood of unintended harmful effects on animals, plants, the environment and bystanders from the use of agricultural chemicals is a potential risk that the APVMA considers when registering new chemicals or reviewing existing chemicals. The APVMA's risk assessments include risk of off-site movement of chemical and ways to mitigate identified risks through label instructions. In assessing the risk of off-site movement, the APVMA considers droplet movement and, where relevant, off-site movement by volatilisation. For example, the APVMA has taken regulatory action to restrict the use of 2,4-D high volatile esters based on volatilisation concerns (www.apvma.gov.au/products/review/current/2_4_d.php).

4. The APVMA is aware of three epidemiological papers published in early 2011, each suggesting that exposure to organophosphates is a marker for poorer cognitive outcomes in children. The studies do not seek to explain how organophosphates might influence childhood learning and achievement.

5. The APVMA will examine whether the findings are relevant to Australian use patterns.

   The APVMA program of spray drift reviews is intended to provide detailed instructions for all spray chemicals to further minimise risks of harm where it is deemed to be likely. Under the APVMA's spray drift policy, label instructions and mandatory no-spray zones require the user to take prevailing wind conditions into account at the time of application before using the products.

6. Most product labels carry general instructions to users regarding management of spray drift risk. The APVMA program of spray drift reviews is intended to provide more detailed instructions for all spray chemicals to further minimise risks of harm where it is deemed to be likely. The APVMA has published the priority candidate list for spray drift reviews which includes some organophosphate chemicals: www.apvma.gov.au/use_safely/spray_drift/priority_list.php

7. Please refer to answer 3.

8. Yes, the APVMA is aware of the paper.

Question: 29 (continued)

9. The time taken to conduct reviews is influenced by the complexity of issues, the amount of data that is submitted, the number of products registered, the range of uses of each product, the number of stakeholders who need to be consulted and the extent and nature of the review outcomes that require implementation.

   There is a perception that an on-going review means the risk that prompted the review is not addressed until the review is finalised. This is not the case. Interim regulatory actions (such as product suspensions with or without new label instructions) and other measures (such as voluntary label amendments, product cancellations and/or formulation changes) are often undertaken prior to the start of a review or early in the review process to address specific areas of concern.

   Nevertheless, clear legislated timeframes, improved data protection and better targeting of risk would reduce the time taken to complete a significant proportion of reviews. These are all issue that are being addressed as part of the Governments reform of the registration and review of agricultural and veterinary chemicals.

10. APVMA assesses all components of a formulated product, including excipients, in determining whether the product is suitable for registration. The APVMA requires and assesses an extensive data package relating to the chemistry and manufacture of the active constituent and the product formulation. All impurities have to be considered and the APVMA will set limits for any impurities of toxicological significance (refer www.apvma.gov.au/registration/morag/index.php) as part of the registration/approval.

11. Australia uses the same regulatory science and assessment frameworks as other countries. All potentially harmful effects are considered in the assessment process and exposure standards are set to ensure that people are not exposed at levels that may cause harm.

12. The APVMA assesses the use of registered products in accordance with proposed label instructions, including consideration of the risk of off-target transport of the pesticides or mixture of pesticides. In addition, where there is evidence about incompatibility of chemicals as mixtures, labels will contain warnings to that effect.

13. The APVMA's current legislative framework (in particular the provisions of section 14 of the Agvet Code) does not permit it to consider the inclusion of markers in pesticides to facilitate tracing of pollution to its source.

    APVMA is not responsible for monitoring but does have regard to any relevant data that is available when making regulatory decisions.

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ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 30

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agvet chemical regulation reform
Proof Hansard Page: Written

Senator Colbeck asked:

1. Can you please explain the statement contained in an APVMA media release on 13 May 2011 titled "Preliminary announcement on agvet chemicals regulation reform"
   "The APVMA and the Department of Agriculture, Fisheries and Forestry are continuing to inform the policy development process and preparing to develop processes to implement the Government's reforms once the specific nature of the reforms has been announced".
2. Can you provide any specific information regarding the status of the policy development?
3. Can you provide any specific information regarding the nature of the Government's reforms?

Answer:

1. The government is doing the work necessary to prepare a draft Bill to improve agvet chemicals regulation for public consultation.

2. A draft Bill is being prepared for consultation with the states and territories and other stakeholders.

3. The Government issued a discussion paper in November 2010. The paper can be accessed at www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 31

Division/Agency: APD/APVMA – Australian Pesticides and Veterinary Medicines Authority
Topic: Pesticide usage
Proof Hansard Page: Written

Senator Colbeck asked:

Sunland Fish Hatchery
In response to QON56, February 2011, you provided some information in relation to an incident in the Sunland area – can you provide an update on the issue and whether there has been a resolution or what remains outstanding to be determined.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) previously advised that it had received six adverse experience reports related to the Sunland area on 27 January 2011. These reports identified headaches in humans, two dead bees, two dead birds, tadpoles with delayed development, chickens with stunted growth and piglets with poor growth rates. The APVMA conducted a preliminary assessment of the information in the reports and liaised with Queensland state authorities to gather any other information that would assist its assessment.

The human health adverse experience report is being considered by the Office of Chemical Safety and Environmental Health in the Department of Health and Ageing with a view to classifying their association with pesticide spraying as ‘Probable’, ‘Possible’, ‘Unlikely’ or ‘Unknown’.

With respect to the animal adverse reports, the reports did not provide any details on the dates of events, relevant post-mortem examinations or results of any laboratory tests. The APVMA requested further information from the Queensland state authorities. This information has been recently provided and is being assessed and the APVMA has not yet made a determination whether pesticides were involved and/or whether regulatory action is warranted.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 32

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Regulatory reforms
Proof Hansard Page: Written

Senator Colbeck asked:

Independent MPs made mention of the APVMA in their agreement with the Government. Can you provide some information on what work has been undertaken for the Government to meet the demands of the Independents and Greens?

Answer:

See response to 30 (APD/APVMA) of Budget Estimates 2011.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 33

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Regulatory reforms
Proof Hansard Page: Written

Senator Colbeck asked:

Can you identify specific examples where the regulatory reforms have or will achieve a reduction in regulatory burden, and provide details of these examples?

Answer:

The reforms to the Australian Pesticides and Veterinary Medicines Authority (APVMA) are being delivered in several waves. The first, which are known as "early harvest" reforms, are largely complete and include:

- Legislation to give effect to a reform on maximum residue limit (MRL) administration came into effect on 1 March 2011. This will see a reduction in the delay between the APVMA's approval of a new chemical use and the publication of an MRL in the Food Standards Code, from 18 months to a maximum of four months. This period may be further reduced in health emergencies.
- Legislation to include trade issues in the definition of "adequate" came into effect on 15 July 2010. This amendment enables the APVMA to initiate a review of a label in response to trade risks, rather than initiating a full product review as was required if label amendments were necessary. This will ensure the APVMA can act promptly to update label instructions to meet the requirements of trading partners.
- The 15 July 2010 amendments also changed the definition of confidential commercial information, to effectively exempt the APVMA from the general prohibition on using confidential commercial information when issuing a permit for minor use or emergency use. This will allow the APVMA to streamline and assess permit applications, without compromising the integrity of the commercial parties involved. It will also reduce the burden on permit applicants.
- Regulations have been amended to formally exclude a range of products from regulation by the APVMA from the National Registration Scheme (NRS) on the basis of risk. These reforms adjusted the structure of the regulations, clarified status of several chemicals and excluded certain products from the NRS.

The second wave of reform, known as the "better regulation" reforms have so far resulted in:

- A change to the process of notifying an approved person, resulting in the removal of a requirement for applicants to notify the APVMA in writing every time there is a change in the actual person nominated as the approved person for the registered approval holder.

Question: 33 (continued)

- Labelling reform that allows companies to make minor changes to chemical product labels, such as changing a logo, without being subject to a further assessment process.
- A notification scheme that simplifies the process for applicants making minor non-technical variations to chemical approvals or registrations (such as changing pack size), instead of requiring a full technical assessment process.

Please see the response to 30 (APD/APVMA) Budget Estimates May 2011 for details of further better regulation reforms.

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Agriculture, Fisheries and Forestry

Question: 34

Division/Agency: APD/APVMA –Australian Pesticides and Veterinary Medicines Authority
Topic: National Framework for Agricultural and Veterinary Chemicals
Proof Hansard Page: Written

Senator Colbeck asked:

1. In response to QON 39 you provided some details about the National Framework for Agricultural and Veterinary Chemicals. Can you provide an update on progress since Additional Estimates?
2. Please provide an overview of the efficiencies expected to be achieved from the proposed reforms to the regulatory system for agricultural and veterinary chemicals.
3. Please provide an overview of the submissions to the Better Regulation of Agricultural and Veterinary Chemicals discussion paper.

Answer:

1. This question is answered in 13 (APD) of Budget Estimates 2011.

2. See question 30 (APD/APVMA) of Budget Estimates 2011.

3. Ninety two submissions were received in response to the Better Regulation of Agricultural and Veterinary Chemicals discussion paper released in November 2010. Public submissions are available at www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/responses-to-the-discussion-paper.

   The primary area of consensus in the submissions was around support for the proposed business improvement measures, including the development of a risk framework, use of clearer statutory timelines, provision of improved data protection, and improving the quality of applications for registration ahead of submitting them to the APVMA.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 35

Division/Agency: APD/APVMA–Australian Pesticides and Veterinary Medicines Authority
Topic: Mouse Plague
Proof Hansard Page: Written

Senator Heffernan asked:

1. What is the APVMA doing to ease the shortage of chemicals available for mice control?
2. Where is the emergency application for Zinc Phosphide at?
3. Does the Minister understand the timeliness of the requirements to have sufficient mouse control?
4. Is the department doing anything to assist the fast tracking of the application in a timely matter?

Answer:

1. APVMA staff have been actively involved in discussions with state departmental officers, the Grains Research and Development Corporation and existing bait manufacturers on current mouse activity and the status of bait supply for registered products. These discussions go back to mid-2010 when, particularly in South Australia, issues began arising. To alleviate pressures on bait availability, the APVMA has been in communications with bait manufacturers on options to expedite bait production and the delivery of product to the market. This interaction between the APVMA, states and manufacturers has resulted in permits being issued to allow registered zinc phosphide products:

- to be manufactured with unsterilised grain because of shortages being experienced in the availability of sterilised grain (permits PER12899 and PER12909)
- to be used around commercial and industrial premises (permit PER12868)
- to be supplied in 500 kg bulk bags (permit PER12741)
- and for the importation and supply of product in 160 kg containers (permit PER12921).

Permits have also been issued to New South Wales livestock health and pest authorities to allow the supply of baits manufactured from bromadiolone (crop perimeter baiting – permit PER11331) and coumatetralyl (around farm buildings – permit PER12845).
Copies of these permits may be obtained from the APVMA website at: www.apvma.gov.au/permits/search.php.

2. On 17 June 2011, the APVMA issued an emergency use permit (PER12837) to 4Farmers Pty Ltd to allow that company to supply a ready-to-use zinc phosphide grain bait to landholders.

Question: 35 (continued)

3. Yes.

4. See answer 2.

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Agriculture, Fisheries and Forestry

Question: 36

Division/Agency: APD/APVMA – Australian Pesticides and Veterinary Medicines Authority
Topic: APVMA Review
Proof Hansard Page: Written

Senator Heffernan asked:

1. Where is the APVMA review up to?
2. Will there be any increase in costs to farmers due to the reform of the APVMA?
3. Where are we up to with the Fenthion and Dimethoate reviews when will those reviews be finalised?
4. You propose decreasing the costs of importing apples through the draft import protocols for NZ and at the same time changes to chemical registrations is likely to markedly increase the costs of exports (by up to 10 times if growers have to move to irradiation). How do you propose managing the competitive advantage that you are giving our industries competitors?

Answer:

1. A draft Bill is being prepared for public consultation, including with the states and territories.

2. The Government has provided $8.75m to implement the reform package.

3. The toxicology components of the reviews of fenthion and dimethoate have been completed. The human health toxicology component for fenthion non-food uses was published in 2005, and the human health and toxicology component of the dimethoate review was published in January 2011. The residues component report for dimethoate is in the final stages of completion; as stated at the February 2011 estimates, it is anticipated that the residues report will be published in July 2011. The similar component report for fenthion is at the assessment stage and not yet ready for finalisation.

4. Import policies for agricultural commodities consider the biosecurity risks associated with particular agricultural commodities. The APVMA is not responsible for this area of Government activity.

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Agriculture, Fisheries and Forestry

Question: 37

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Chemical Use
Proof Hansard Page: Written

Senator Back asked:

1. Is APVMA aware of the volatility of the registered organophosphate insecticide trichlorfon, which is applied to macadamia orchards amongst other crops, by air blast mist spraying?
2. Is it aware that trichlorfon breaks down into dichlorvos which is substantially more volatile and documented to readily move off-site of its application?
3. Is the APVMA aware of the Canadian review of trichlorfon 2008 which identified considerable risk remained after application to orchards for humans, for days, due to volatising dichlorvos?
4. Why was the Minister, Joe Ludwig, advised by Greg Williamson (DAFF) that there was no volatility risk associated with the use of trichlorfon in his response to a letter from Dr Matt Landos?
5. Does the label of these products require its use to ensure safe wind directions, during the entire period of spray application and the days of volatising afterwards to ensure, neighbouring properties people and animals are unexposed?
6. Is it meteorologically normal for the wind blow from the same direction continuously all day and night for days at a time?
7. If not, how can APVMA be satisfied that there is adequate control of the off-site movement of a vapour hours to days after application?
8. Is the APVMA aware of the CSIRO guidelines for spray application which highlight the climatic conditions particularly at night, and in warm conditions which enhance off-site movement?
9. Given trichlorfon is applied during northern rivers spring and early summer, has the APVMA risk assessment which permits use, accounted for the climatic conditions at that time which are hot and conducive to drift?
10. Given the detection of dichlorvos on a testing strip inside a fish hatchery building, adjacent to a macadamia farm, time coincident with the application of trichlorfon on a neighbouring macadamia farm, has the APVMA assessed the cumulative inhalational and dermal exposure risks for neighbours of macadamia farms?
11. Why has the APVMA not acquired the Qld Noosa Fish Health Investigation Taskforce final report, and the reports of the assisting scientists to assist in its investigations of Adverse Event reports lodged in October 2008 and subsequently?
12. Why has it not sent out the report of Dr Matt Landos, which was provided to it by Dr Landos, to its independent scientists for review?
13. Is APVMA aware of the recently published US epidemiological studies linking the impact of exposures to Organophosphates on diminishing children’s IQ?

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ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2011

Agriculture, Fisheries and Forestry

Question: 37 (continued)

14. Is the APVMA aware of the Australian epidemiological paper demonstrating enhanced risk of non-hodgkins lymphoma in person's occupationally exposed to pesticides?
15. Why does the APVMA permit use of this product on macadamia orchards when there are residential houses in close proximity (many under 100m) to many orchards around the Northern Rivers of NSW and South East Queensland?
16. Why were trichlorfon products not included in the APVMA review of Dichlorvos, when it is fact that it breaks down into that compound?
17. Why has the dichlorvos review taken 15 years to complete?
18. What legislative changes or resourcing changes would assist the APVMA in completing reviews in under 12 months from the time of initiation?

Answer:

1. Yes.

2. The APVMA is aware that trichlorfon breaks down to dichlorvos.

3. Yes, the APVMA is aware of the findings of the Canadian 2008 review of trichlorfon. The review identified the potential for dermal and inhalational risks from both trichlorfon and its dichlorvos breakdown product. The inhalation risks were assessed as low and risk mitigation measures in the form of re-entry intervals were implemented based on dermal exposure to leaf surface residues.

4. It is incorrect to say that the Department of Agriculture, Fisheries and Forestry (DAFF) advised the Minister that "there was *no* [emphasis added] volatility risk associated with the use of trichlorfon" in its response to Dr Landos. The department advised the Minister that none of the registered organophosphate chemicals registered for use in macadamias is 'significantly volatile'. This is consistent with advice the department received from the APVMA.

   In addition, the Department of Sustainability, Environment, Water, Population and Communities advised that impacts on fish aquaculture from the nearby use of trichlorfon would be *highly unlikely*, given the past use of this chemical on fish to treat sea lice. The therapeutic concentrations used to treat fish are expected to be significantly higher than concentrations likely to be detected at the fish hatchery from nearby use. Therefore, it is highly unlikely that the use of trichlorfon would pose a volatility risk to aquaculture.

5. The two product labels currently do not provide detailed instructions on wind direction during or after application. One of the two product labels specifies that the product is not to be applied under weather conditions or from spray equipment that may cause spray drift. The APVMA's spray drift policy which outlines the models that are to be used to assess spray drift risk and risk

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mitigation for specific situations did not come into effect until July 2008, and trichlorfon products have not yet been assessed for spray drift risk. Trichlorfon is a Priority 1 chemical for review on APVMA's priority list. The APVMA will conduct a spray drift risk assessment as part of the review, when it commences. The risks arising out of the potential for volatilisation will be considered as part of the review.

6. The APVMA is not qualified to answer and information should be sought from the Bureau of Meteorology.

7. The APVMA spray drift policy recognises that the risk mitigation strategies relate to risks 'downwind' at the time of application. The risks arising out of the potential for volatilisation are also considered. For example, the APVMA has taken regulatory action to restrict the use of 2,4-D high volatile esters based on volatilisation concerns (www.apvma.gov.au/products/review/current/2_4_d.php). The APVMA review will consider any potential risks from volatilisation when it conducts the review referred to in Question 5.

8. The APVMA is aware of the CSIRO guidelines as well as a number of published guidelines for spray application, which highlight the need to have regard to climatic conditions with respect to spray application. Detailed information is available on the APVMA website at www.apvma.gov.au/use_safely/spray_drift/inversions.php.

9. Pesticide products containing trichlorfon were originally assessed and registered by states and territories and grandfathered into the National Registration scheme at the time of its commencement. The APVMA has not yet conducted a spray drift risk assessment for products containing trichlorfon. A review of trichlorfon is scheduled as a priority 1 chemical review and will include a comprehensive spray drift assessment.

10. The APVMA is aware of a detection of 55 nanograms of dichlorvos (the reporting laboratory does not assay for trichlorfon directly but converts it to dichlorvos for the assay) on a filter paper in the hatchery. However no dichlorvos was detected in samples from a fish pond taken at the same time. The level of dichlorvos detected on the filter paper has been assessed as not presenting a risk to bystanders. Trichlorfon is currently placed as Priority 1 chemical for review on APVMA's priority list and human bystander risks will be assessed as part of this review.

11. The APVMA was provided with all component veterinary reports and several supplementary reports to assist it in the classification of various adverse events at the hatchery. The final report of the taskforce was not released by the Queensland Government until Wednesday 8th June 2011.

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12. The APVMA assessed the final report from Dr Landos together with the reports already received from the scientific experts. The APVMA did not seek further advice from the experts as the final report did not contain significant new information compared to the large amount of material already provided to the APVMA which included the original report, the seven veterinary reports plus further information provided by the Taskforce. The APVMA may however seek further expert advice on the final report from Dr Landos as well as all the documents from the Taskforce when they are made available.

13. Yes, the APVMA is aware of three epidemiological papers that were published in early 2011 each suggesting that exposure to organophosphates is a marker for poorer cognitive outcomes in children. The studies do not seek to explain how organophosphates might influence childhood learning and achievement but warrant further consideration.

14. No, the APVMA is not aware of the Australian epidemiological paper referred to in this question. However the APVMA is aware of an overseas epidemiological paper regarding occupational exposure to pesticides and Non-Hodgkin's Lymphoma. According to the US Lymphoma Research Foundation, the causes of non-Hodgkin's Lymphoma remain unknown, but immune system impairment and exposure to environment carcinogens, pesticides, herbicides, viruses and bacteria may play a role. In general, epidemiological papers are only useful in a regulatory context if a direct link can be established, and additional research is then needed to establish whether a cause and effect relationship exists.

15. Pesticide products containing trichlorfon were originally assessed and registered by states and territories and grandfathered into the National Registration scheme at the time of its commencement. The human health risks of trichlorfon were evaluated in Australia in 1993, 2000, and 2005 and trichlorfon is a Priority 1 chemical for review on APVMA's priority list. The APVMA will conduct a spray drift and bystander risk assessments as part of the review, when it commences. To date there has not been sufficient evidence to indicate immediate regulatory action is warranted.

16. The APVMA advises that its review of dichlorvos focussed on its use as a fumigant. Trichlorfon is not used as a fumigant.

17. APVMA's review of dichlorvos (see www.apvma.gov.au/products/review/completed/dichlorvos.php) explains why the finalisation of this review was delayed.

18. See response to 29 (APD/APVMA) Budget Estimates 2011, Part 9 of response.