Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 52

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Summerfruit data by Horticulture Australia

Proof Hansard page: 72

Senator LINES asked:

Senator LINES: Where was Summerfruit's data gathered from?

Dr Bhula: Summerfruit's data was the data supported by Horticulture Australia, so that was the best set of data that we had.

Senator LINES: But where did it come from?

Dr Bhula: It came from all over.

Senator LINES: Sorry, I don't know what you mean by 'all over'.

Dr Bhula: They had generated data in Western Australia as well as New South Wales and Queensland.

Senator LINES: Whereabouts in Western Australia?

Dr Bhula: I would have to take that question on notice.

Senator LINES: Nobody there knows?

Dr Bhula: It is available in our report. We can look that up and get it for you.

Senator LINES: How much data was taken from Western Australia? I would be interested in knowing how much and where.

Dr Bhula: There were a couple of field trials—two, I think. We can take that on notice and answer for you.

Senator LINES: Two field trials.

Dr Bhula: And there were a couple of field trials in Queensland and a couple of field trials in New South Wales.

Answer:

Summerfruit submitted residues data from a total of 10 trials. Four of those trials were conducted in the Perth Hills area, two in Victoria, two in New South Wales and two in Queensland.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 53

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Cost of Clothianidin

Proof Hansard page: 81

Senator STERLE asked:

Dr Bhula: They still have access to the Clothianidin if they choose to use it.

Senator STERLE: Is that cost anywhere near the Fenthion? Why won't they use it now?

Dr Bhula: We would have to take the cost question on notice, I am afraid.Is that cost [of clothianidin] anywhere near the Fenthion? Why won't they use it now?

Answer:

Yes. Industry estimates from Western Australia are that the costs per application are $108.11 per hectare for fenthion and $115.20 per hectare for clothianidin.

The Authority is not aware of reasons for individual grower decisions.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 55

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Is the current permit for fenthion subject to further change?

In October 2012, APVMA Executive Director, Raj Bhula, told around 40 growers at a public meeting held at the Canning Vale markets 'that growers wanted to hurt children' because they wanted to use fenthion'.
Does the APVMA still stand by Dr Bhula's statement?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) does not agree that the quote attributed to Dr Bhula is accurately stated. However the APVMA stands by the decision to restrict the use of fenthion due to health and safety concerns. The APVMA makes decisions on the best available science at the time of the decision. If further evidence is provided to support further changes, this evidence will be considered.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 84

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

To whom does the APVMA believe it is accountable to?

Answer:

The principal responsibilities of the Australian Pesticides and Veterinary Medicines Authority (APVMA) are outlined in the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals Code Act 1994* which set out the regulatory framework for the management of pesticides and veterinary medicines in Australia. The APVMA performs a national regulatory role and is accountable to the Minister for Agriculture.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 93

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

According to FreshTest data, which has been compiled over the past decade containing tens of thousands of samples from random sample testing conducted with produce collected from wholesale markets around Australia, in which 98% of fresh produce showed a Nil Residue return for fenthion. This was during the period when the Pest Free Areas (PFA's) were still under care and maintenance. In an effort to keep fruit fly out of these valuable PFA's the Victorian State Government legislated under ICA21 that produce entering Victoria from another State had to be sprayed with fenthion around 5-7 times in order to ensure that the imported produce was fruit fly free. The standard usage pattern in Western Australia was 1-2 applications, with a 3rd application available in times of extreme fruit fly instigated crop losses. The current APVMA permit allows up to 3 applications on nectarines and plums. Considering that 98% of produce was returning a nil fenthion residue detection at a time when fenthion was being applied at around twice the current permit for nectarines and plums and 5-7 times the current permit for peaches and apricots, does the APVMA concede that it has overreacted and been unfairly harsh and contributing to the annihilation of the Australian peach and apricot industry in issuing a permit with only 1 application for these 2 fruits?

Answer:

Quality assurance programs, such as FreshTest, test to ensure a product is safe to use/consume at the point of sale. Residue data from quality assurance programs is of limited use for regulatory purposes, such as setting standards and assessing whether the risks associated with dietary exposure will be acceptable to all segments of the population.

There are many reasons for this, including deviations from label instructions, lack of sprayer records to substantiate use, samples not being stored correctly before analysis, full residue definitions not always being addressed in the testing due to costs, samples collected not being treated with the chemical in question and differing times from time of spray to harvesting and sampling.

The regulator has to ensure that a product is safe to use/consume as per the label instructions, ie at the withholding period stated on a product label. Quality assurance programs, such as

Question: 93 (continued)

FreshTest, are testing at the time of sale, which may be much longer than the withholding period required on the label.

For a use to be approved, or continue to be approved, all food treated with a pesticide must be safe for consumption at the time of harvest. Studies used to support such an analysis must therefore be conducted according to OECD principles of Good Laboratory Practice (GLP).

The GLP data submitted by Summerfruit Australia Ltd showed that detectable residues are expected on peaches and apricots at harvest 14 days after the second of two applications of fenthion.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 98

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Australian grown produce is subject to random sample testing for 135 different residues as part of producers' Quality Assurance programs, imported produce is subject to only 50 residues when tested. Does the APVMA show any concern for the residues that are on imported produce, or do foreign residues not pose any risk to Australian consumers?

Answer:

Residues on imported produce is beyond the scope of Australian Pesticides and Veterinary Medicines Authority's legislative responsibilities.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 100

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Has the APVMA latest Residues and Dietary Exposure Assessment, released on October 16th 2013, been independently peer reviewed and if so how many peer reviews did the assessment undergo?

Answer:

The *Supplementary Fenthion Residues and Dietary Risk Assessment Report* of October 2013 was peer reviewed internally according to Australian Pesticides and Veterinary Medicines Authority (APVMA) standard practices and has been published on the APVMA website (see www.apvma.gov.au/products/review/current/fenthion.php).

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 107

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA acknowledge that 11 months' work have gone into raising stone fruit crops to the point of harvest and to remove fenthion from usage caused great trauma and crop losses to stone fruit growers?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) issued a 12 month permit in October 2012 for restricted use of fenthion on certain produce. Industry submitted residues data in July and August 2013. The APVMA released its decision to extend the permit, except for use on peaches and apricots, as soon as practicable, based upon the available data and the restricted use patterns provided under the October 2012 permit.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 109

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

The APVMA's latest Residues and Dietary Exposure Assessment has been independently reviewed by Mark Imisides Phd (Chem), and I ask the following questions;

1. The APVMA's conclusions of an unacceptable risk hazard to children aged 2-6 years old are all based on an ArfD (Acute Reference Dose) of 0.007mg/kg body weight. Fenthion is one of the few pesticides for which human data is available, and the NOEL (No Observable Effect Limit) is 10 times that – at 0.07mg/kg. That is, clinical data says that you can have 0.07mg/kg of fenthion in your blood and there is no observable effect. Not only is there no observable health effect, but there is no effect whatsoever. Why has the APVMA applied a 10 fold safety factor in using the ArfD, when there is clear evidence of no effect in humans whatsoever (in health or otherwise) at the NOEL level of 0.07mg/kg?

2. Is it common practice for 10 fold safety margins to be implemented in cases where there is no human data available?

3. Has the APVMA deliberately applied an unnecessary ten fold safety margin on a nil effect NOEL in order to highly reduce the probability of fenthion to be able to be used against Med Fly and still remain under the MRL during random sample testing?

4. In the APVMA's Residues and Dietary Exposure Assessment, the onus of proof is backwards. The report is written as though fenthion is a new product seeking registration. This can be the only possible interpretation of a report which contains the word 'likely'. If there is over 50 years of data regarding the public health of the use of this product available, as well as human testing data, no speculation is required. The history of the product should be the final arbiter in terms of health effects. The definition of proof is 'evidence or argument establishing a fact or the truth of a statement'. Has the APVMA been able to prove anything in this report regarding the risks of adverse health or is the report based solely on a mathematical calculation of supposed risk?

5. As the APVMA are unable to prove any element of risk and there is no statistical analysis of risk, the APVMA's approach is thoroughly inconsistent with their complete reliance upon physical statistical information to generate their mathematical prediction. Armed with all statistical information the APVMA should be able to predict the rate at which people will get sick, eg what number in every 1000 peaches will cause a child aged 2-6 years old a health

Question: 109 (continued)

problem. The APVMA claim, rightfully, that this is not part of their charter to conduct statistical analysis. However, given the public controversy and doubt surrounding this APVMA's claims regarding risk of harm, will the APVMA conduct a statistical analysis of risk to help add clarity to the fenthion issue and assist in proving the APVMA's claims?

6. If not, why not?

7. Does the APVMA believe that a statistical analysis would strengthen or weaken their claim?

8. (If the answer is strengthen) Will the APVMA conduct a statistical analysis of risk and open their process and data of risk calculation to public scrutiny?

Answer:

1. A 10 fold safety factor was used by the Office of Chemical Safety within the Federal Department of Health when they established the Acute Reference Dose (ARfD) for fenthion in 2000. This safety factor is used to account for variation in sensitivity of chemicals to ensure that the most vulnerable individuals in the population are protected. This is particularly important as most study participants are adult, healthy males with no pre-existing health conditions. See http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-arfd-list.htm for details.

2. No. Greater safety factors of 100 fold or higher are commonly applied to animal studies unless there are exceptional circumstances that allow the use of a lower safety factor.

3. No. Please refer to the answer to Question 1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) does not set the ARfD.

4. The APVMA has followed the standard procedures for residues and dietary risk assessment of an existing chemical. The report is based on the known residues results for each use pattern assessed, the established public health standards for fenthion and the Food Standards Australia New Zealand (FSANZ) dietary consumption figures that are based on surveys of Australian food consumption.

5. No. A statistical assessment is not part of the protocols for dietary risk assessment that have been agreed with FSANZ.

6. Please refer to the answer to Question 92 Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority from the supplementary Budget Estimates hearing in November 2013 for more information.

7. The APVMA has no opinion on the outcome of such an assessment.

8. Please refer to the answer to Question 7.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 110

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Diuron

Proof Hansard page: Written

Senator MACDONALD asked:

In answer to questions during Budget Estimates hearings in May 2013 regarding the restrictions placed on the use of Diuron – and the resulting requirement for Canegrowers to use more expensive alternatives – the Department indicated that it would reconsider the restrictions if it was warranted by future monitoring and data.

1. Does the restriction on the use of Diuron remain in place?
2. Has the agency investigated the previous findings?
3. Has any new evidence been presented since May 2013?
4. Has the Department made any internal or independent investigations into the data?

Answers:

1. Use of Diuron products is only permitted in accordance with approved label instructions which include limited periods of application and restraints to protect waterways from chemical runoff.

2. No further consideration of Diuron has been undertaken since completion of the review in November 2012.

3. No new information has been made available to the Australian Pesticides and Veterinary Medicines Authority (APVMA) since May 2013.

4. The APVMA has not investigated the availability of information that may change the decision on Diuron made by the APVMA in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 111

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

How did the decision to restrict the use of Fenthion come about?

Answer:

The review of fenthion commenced in 1998. As a consequence of the review of the toxicology of fenthion, the federal Department of Health established a new public health safety standard that included short-term exposure to fenthion. Inclusion of short-term exposure to fenthion in the new standard meant that a residues and dietary exposure risk assessment was required to assess whether any of the approved uses of fenthion could lead to dietary exposure to fenthion above the new public health standard.

This assessment, by the Department of Health, which is documented in the *Fenthion Residues and Dietary Risk Assessment Report*, September 2012, found that the use of fenthion on certain crops could lead to exposures to levels of fenthion in treated produce above the new public health standard.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) announced that it proposed to take regulatory action to issue new instructions for the use of fenthion to ensure that consumers remain protected when products are used according to those instructions. In September 2012 the APVMA called for the submission of information that could be used to develop instructions for the use of fenthion

The APVMA considered all submissions relating to proposed modifications to use patterns to reduce potential dietary exposure concerns. The APVMA considered all available residues trial data and information provided by growers, together with residue monitoring results to develop the new instructions for use. These were an interim set of instructions for the suspension period only, which was due to expire October 2013.

Further information relating to residues resulting from the use of fenthion on stonefruit and the results of monitoring of residues in commercial fruit was submitted to the APVMA in July and August 2013. This information was assessed and it was concluded that the potential dietary exposure resulting from the use of fenthion on peaches and apricots exceeded the health standard and that the withholding period for use of fenthion on nectarines and plums should be amended to 14 days.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 114

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Reinstate Fenthion

Proof Hansard page: Written

Senator STERLE asked:

Prior to the election, the Coalition pledged to reinstate Fenthion. Has Minister Joyce now followed the advice of the APVMA?

Answer:

The principal responsibilities of the Australian Pesticides and Veterinary Medicines Authority (APVMA), as an independent regulator, are outlined in the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals Code Act 1994 which set out the regulatory* framework for the management of pesticides and veterinary medicines in Australia.

The APVMA uses a science-based approach to decision making, which includes consideration of all available data at the time a decision is being made. If new, credible data or information becomes available or is submitted, previous conclusions are reconsidered in light of the new information. The APVMA, not the Minister for Agriculture, has made decisions in relation to use of fenthion in accordance with this regulatory framework.

The chemical review of fenthion resulted in the finding that certain previous uses on existing labels of fenthion products were not acceptable. Industry submissions since September 2012, that included information proposing alternative uses of fenthion and then the submission of new data, have been assessed against the public health standards for safe exposure to fenthion. This resulted in permits being issued with modified instructions for use of fenthion products and exclusion of use on peaches and apricots. These permits are current until 30 October 2014.

A separate permit application was made by Summerfruit Australia requesting the use of a single spray of fenthion only for peaches and apricots. Following an assessment, the APVMA issued a new permit, valid from 29 October 2013 to 30 April 2014 which allows growers to apply a single spray of fenthion to peaches and apricots 21 days before harvest.