Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 54

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Has the APVMA, an independent public safety regulator using science as the basis for its regulation practices, had 5 different positions on the risk that stone fruit treated with fenthion poses to consumers from the period of August 2012-October 2013?

The APVMA has held five positions on the safe level on the use of fenthion since August 2012;

1. Consumption of edible skinned produce treated with fenthion is safe (ongoing permit up until suspension in Sept 2012)

2. Consumption of edible skinned stone fruit treated with fenthion is unsafe (fenthion suspended Sept 2012

3. Consumption of edible skinned stone fruit treated with fenthion is safe (permit issued October 2012)

4. Consumption of edible skinned stone fruit treated with fenthion is safe, except for peaches and apricots treated with fenthion, which is unsafe (permit & suspension Oct 2013)

5. Consumption of edible skinned stone fruit treated with fenthion is safe (permit Oct 2013)

a. Which one of these positions is correct?

b. Which position does the APVMA stand by now as safeguarding public health?

Answer:

The APVMA uses a science-based approach to decision-making, which necessitates consideration of all available data at a particular point in time. If new credible data or information becomes available or is submitted, previous conclusions must be reconsidered in light of this new information.

As part of the review of fenthion, the APVMA, at different times following the release of the 2012 report, has assessed three sets of new information from industry that proposed alternative ways to apply fenthion (reduced sprays, increased withholding periods).

Question: 54 (continued)

The public health standards for safe exposure to fenthion have not altered since they were established as part of the review of fenthion in 2012. The various proposals from industry about alternative uses of fenthion have been assessed against these public health standards since September 2012. This has resulted in the varying conclusions made over this period.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 56

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Why was fenthion deemed to have an unacceptable level of risk to the public through edible skinned fruit consumption in September 2012 when a suspension was imposed, yet deemed to be safe for public consumption of the exact same produce in October 2012 when a permit for usage was issued?

Answer:

The permit in October 2012 was based on modified, reduced use instructions for fenthion on stonefruit that limited the number of sprays and increased the withholding period. These changes to the use patterns decreased the potential dietary exposure to fenthion residues from eating treated fruit that were identified by the APVMA in September 2012.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 57

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

The APVMA banned the usage of fenthion on peaches & apricots on October 16th 2013 due to unacceptable risk to consumers.

1. Was any new fenthion data submitted to the APVMA in between the dates of October 16th 2013 and October 29th 2013?

2. What was the reason for the APVMA to reverse the October 16th 2013 ban on peaches and apricots and issue a permit for 1 application for these fruits on October 29th 2013?

3. Did fenthion suddenly change from being an unacceptable risk, to safe for consumption in just 13 days?

Answer:

1. No new data was submitted between 16 October 2013 and 29 October 2013.

2. On 20 October 2013, Summerfruit Australia requested the APVMA to consider a reduced use pattern for fenthion on peaches and apricots, involving a single spray and 21 day withholding period. Summerfruit Australia followed the request with a formal application for a permit on 25 October 2013.

Based on analysis of available data, the APVMA was able to issue a separate permit for peaches and apricots only on 29 October 2013, as the changes to the use patterns decreased the potential dietary exposure to fenthion residues from eating treated fruit. This permit (Number PER 14501) is effective to 30 April 2014.

3. The reduced use pattern proposed by Summerfruit Australia was assessed as having a lower, acceptable dietary exposure to fenthion arising from eating treated fruit.

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Agriculture

Question: 58

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

In October 2013 the APVMA issued a permit for clothianidin (Trade name Samurai) for usage against Mediterranean Fruit Fly.

1. Did the APVMA cut any assessment corners whatsoever in the issuing of the permit for clothianidin against Med Fly? If so, why?

2. Does the APVMA normally refuse to use data generated overseas or foreign regulators' decisions into account when assessing product suitability for registration or re-registration?

3. Did the APVMA take into account any overseas generated data or foreign regulatory decision in its own registering of clothianidin for usage against Med Fly?

4. Did the APVMA have data from a laboratory test conducted to determine the efficacy of clothianidin against Med Fly?

5. Did the APVMA have any infield data relating to the efficacy of clothianidin against Med Fly? If the APVMA did have infield data, was this data complete to the point that the same data on other potential chemical registrations would be? If the APVMA did not have data, why did the APVMA not wait for the generation of infield data before issuing the permit for clothianidin?

6. Did the APVMA have a significant and comprehensive data package as well as infield data to consider when issuing the permit for usage of clothianidin against Queensland Fruit Fly?

7. In making the ill-considered decision to issue a permit for clothianidin usage against Med Fly, did the APVMA merely just view the data generated from comprehensive Queensland fruit Fly testing and apply it to Med Fly?

8. Is this common practice for data assessment, to accept data from one particular section of the target pest family and apply it with a broad brush across all other sections, regardless of efficacy? If not, then why now?

9. Does the APVMA take into account potential environmental damage when assessing a new product for registration?

Question: 58 (continued)

10. Why did the APVMA issue a permit for clothianidin in the same period that the chemical is being suspended across Europe under suspicion of causing mass bee trauma and 'Bee Colony Collapse Disorder'?

11. Is Sumitomo the manufacturer of Samurai (active ingredient clothianidin)?

12. Is Dr Gordon Reidy both a member of the APVMA's Advisory Board and also a Regional Manager under the employment of Sumitomo?

13. Does the APVMA consider that there is any conflict of interest in having the Regional Manager of Sumitomo on its Advisory Committee, when the manufacturer's product has been fast tracked through the registration process?

14. How did Samurai get approved so fast for usage against Mediterranean Fruit Fly – is it because Mr Reidy is on the APVMA's advisory board?

15. Did Mr Reidy have any involvement whatsoever in Samurai receiving a permit for usage against Med Fly so quickly?

16. Did the APVMA fast track a permit for the usage of clothianidin against Med Fly as a substitute for fenthion?

17. If not, why is the APVMA promoting clothianidin as an effective solution to fruit fly control to politicians?

18. The Hills Orchard Improvement Group in its data submission recommended that a further trial be conducted during the 2013-14 growing season of a reduced rate of fenthion application of 50ml (Lebaycid) per 100L (water). What was the APVMA's response to this proposal?

19. Why did the APVMA issue this response in the negative?

20. In March 2013, the US EPA was sued by a coalition of beekeepers, as well as conservation and sustainable agriculture advocates who accused the agency of performing inadequate toxicity evaluations and allowing registration of the pesticides to stand on insufficient industry studies. Does the APVMA admit that they may have placed themselves in the same situation in Australia, where the APVMA may be sued for inadequate evaluations?

21. Is the APVMA aware of legal action being taken by a coalition of beekeepers against the US EPA stemming from their registration of clothianidin?

22. Following the APVMA's evaluation of clothianidin in 2007 it is stated 'The Australian Pesticides and Veterinary Medicines Authority notes that clothianidin ranks "among the most highly acutely toxic insecticides to bees" through contact and oral exposure.' Why has the

Question: 58 (continued)

APVMA issued a permit for usage against fruit fly when the consequences of a registration could be catastrophic for Australian bee populations?

Answer:

1 – 10, 16-17. Clothianidin has previously been assessed and registered for use on apples, pears, peaches and nectarines.

On 31 May 2013 Growcom lodged a permit application with the APVMA requesting an extension to allow clothianidin to be used for the control of fruit fly on all pome fruit, stone fruit and persimmons. The use pattern in terms of rate of application and number of sprays requested was identical to that already registered for other insect pests.

Growcom requested that the APVMA grant the permit based on previously evaluated Australian and overseas residues data, new data on efficacy for Queensland and Mediterranean Fruit Fly and registration in the US for control of the related Tephritid (Walnut Husk Fly) and Drosophilid (Spotted Wing Drosophila) species in various fruits.

The APVMA considered the submission provided by Growcom and the supporting data and evidence provided. This involved assessments of residues in treated produce for both new crops and a reduced withholding period by APVMA evaluators as well as efficacy through input from states and territories.

The APVMA was satisfied to issue a permit on 5 September 2013 on the following grounds:

- an assessment of the available Australian and overseas clothianidin residue data supported an extension to all stone fruit, pome fruit and persimmons under the proposed use pattern observing a maximum of two sprays per crop with a seven day withholding period
- an assessment of the limited clothianidin efficacy data, overseas registrations against related species and support received from states and territories for enabling access to new options that may assist growers in the control of fruit fly
- current research is proving promising and grower industries are seeking earlier introduction of products rather than waiting several years before complete studies required for full registration are available. The APVMA notes that industry has conducted screening trials for up to 15 different alternatives to fenthion and clothianidin has been identified as a promising option in controlling fruit fly.

11 – 15. Sumitomo Chemical Australia Pty Ltd is the registrant of Samurai Systemic Insecticide. The permit for clothianidin issued on 5 September 2013 was to Growcom, not Sumitomo. The

Question: 58 (continued)

APVMA is not aware of what involvement, if any, Dr Gordon Reidy has in relation to Samurai. Dr Reidy's membership on the APVMA Advisory Board had no bearing on the progression of the permit.

18 – 19. There is nothing precluding HOIG from conducting further trials. If further residues data or alternate use patterns are submitted for assessment, then the APVMA would assess the applications in the usual manner.

20 – 22. All insecticides have the potential to kill bees if not used according to label instructions. Products containing clothianidin are registered for use on a range of pests on crops including apples, pears, peaches and nectarines. A full registration assessment including environmental impacts of a wide range of studies was conducted (see www.apvma.gov.au/registration/assessment/docs/prs_clothianidin.pdf).

Bees are recognised as a beneficial insect and the use instructions and warnings on product labels and permits are carefully assessed to give suitable protection for bees. This includes consideration of appropriate times to apply products before crop flowering and good agricultural practices that limit risk arising from overspray onto flowering weeds and/or bees foraging on treated fallen fruit. Registered products and permits contain such information in their instructions. The registration assessment for clothianidin products recommended label instructions that clothianidin is dangerous to foraging bees or bees in hives that are over-sprayed or reached by spray drift, and that residues may remain toxic to bees for several days after application. Flowering crops should not be treated with clothianidin.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 59

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

There are 3 organophosphates, Fenthion (Lebaycid), Trichlorfon (Lepidex), Malathion (alternate name, Maldison depending on country) currently registered in some way shape or form for usage against fruit flies on edible skinned fruit in Australia.

1. Does the APVMA recognise that Dichlorvos is a transformation product of Trichlorfon as it breaks down in human bodies?

2. Does the APVMA recognise that Dichlorvos is up to 100 times more active as a cholinesterase inhibitor than trichlorfon?

3. Does the APVMA recognise that Dichlorvos is mutagenic and clastogenic in-vitro, as detailed on page iv of their own Toxicology Assessment, June 2008?

http://www.apvma.gov.au/products/review/docs/dichlorvos_tox.pdf

4. Does the APVMA recognise that Malathion (alternative name, Maldison) breaks down into Malaoxan, which is a compound 61 times more toxic than its parent?

5. Does the APVMA recognise that fenthion breaks down into a safer compound in the natural environment as time elapses after initial application?

6. Does the APVMA recognise that there is not one documented case of harm or death from the ingestion of fresh produce treated with fenthion, despite over 50 years of usage world wide?

7. Why is the APVMA attempting to remove fenthion from usage, yet recommending more harmful products on the APVMA's own website for usage against fruit fly?

http://www.apvma.gov.au/products/review/current/dimethoate_alternatives.php

Question: 59 (continued)

Answer:

The World Health Organisation (WHO) has classified active ingredients of pesticides according to their acute toxicity. The latest report classifies both fenthion and trichlorfon as moderately hazardous and maldison (malathion) as slightly hazardous.

However, comparisons of the relative toxicity of chemicals (that is, the potential of a chemical to cause harm) does not provide a meaningful insight into the actual level of risk that a chemical poses to humans. Chemical risk assessment also involves an examination of how much of the chemical people actually come into contact with (that is, the exposure to the chemical).

The review of fenthion has included an examination of the toxicity of fenthion and also of the potential dietary exposure of people to fenthion. The Federal Department of Health established the health standard for fenthion. The APVMA then assessed the dietary exposure risk from fenthion to determine if the health standards would be breached if fruit was sprayed according to the use patterns in question. The analysis of data submitted in 2013 resulted in the APVMA placing restrictions on the use of fenthion on peaches and apricots as the APVMA could not be satisfied that the health standards could be met. In conducting this assessment, the APVMA considered residues of fenthion and five breakdown products of fenthion, as they are as toxic, or more toxic than fenthion itself.

The APVMA does not recommend chemical alternatives to fenthion or any other pesticide but provides advice in relation to registered chemicals available for control of certain pests such as fruit fly. This advice makes no recommendations regarding the effectiveness of these products for the particular situation.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 60

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

During a phone conversation held on October 16th 2013 between members of the Fruit Fly Action Group (a sub-committee of the Hills Orchard Improvement Group) and employees of the APVMA, Dr Jason Lutze (the APVMA's manager of pesticide residue) claimed that 'Fenthion is a contact insecticide – there is very little systemic activity'.

1. Does the APVMA still stand by this statement?

2. Does the APVMA truly understand fenthion (and other chemicals that they assess) if the APVMA can get such a fundamental aspect of fenthion incorrect?

Answer:

1. Yes. In the context of the discussion the statement was correct. Fenthion has only a very slight systemic effect in plants. It will transfer across the skin of sprayed fruit to act on larvae in the fruit but does not exhibit significant movement around the plant. It is not, for instance, approved for use for soil application for control of pests of leaves or fruits.

2. Yes. The APVMA understands the nature of fenthion.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 61

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

In 2012 did the APVMA set the parameters by which the Hills Orchard Improvement Group (HOIG) would conduct its random sample testing during the 2012-13 season in order for HOIG to provide the regulator with residue levels, which from the data would be used to issue/or otherwise a permit for usage for the 2013-14 season?

1. Did Jason Lutze instruct HOIG to test for residues in accordance with the 'Sum of Fenthion'?

2. Is the 'Sum of Fenthion' exactly defined as - Sum of fenthion, its oxygen analogue and their sulphoxides and sulphones, expressed as fenthion (fat-soluble)?

3. Did the APVMA also confirm in correspondence with Fruit West, that testing should be done to the 'Sum of fenthion, its oxygen analogue and their sulphoxides and sulphones?

4. Does the APVMA concede that HOIG conducted its testing according to the 'Sum of Fenthion' as directed?

Answer:

The APVMA discussed the residue trial requirements with HOIG in late 2012. In an email dated 30 October 2012, the requirement for Good Laboratory Practice trials as well as ongoing residue surveillance for stone fruit was detailed. This was followed by an email and verbal discussion on 2 November 2012. The email provided some details of what was required of the surveillance program, including what information was needed for each sample, the number of samples required and that the APVMA residue definition must be followed.

Following further contact by HOIG on 5 November 2012, the APVMA provided advice on the appropriate number of trials to be conducted according to Good Laboratory Practice. The APVMA also advised HOIG to employ an experienced consultant or GLP trial provider to assist in residue trial protocol development.

1. No. The complete Australian residue definition was referenced.

Question: 61 (continued)

2. No. The Australian residues definition is the *Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion.*

3. Yes.

4. No.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 62

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA also concede that during the 2012-13 harvest season, testing was being conducted by Agrifresh in conjunction with industry levies and peak body involvement?

1. Is it best practice for trials to be conducted in accordance with Good Laboratory Practice protocols?

2. Did the APVMA stick to GLP protocols, or did the regulator make any unusual concessions or adjustments to GLP protocols?

3. Did these changes revolve around different air-blast spray applicator units not being calibrated to the same volume output?

4. HOIG requested that the Agrifresh data be peer reviewed, did the APVMA carry this out?

5. If yes, was the peer review conducted by an independent body or does the APVMA have a pre-existing relationship with the body of peer review in this instance?

Answer:

The question references Agrifresh. Agrisearch (not Agrifresh), on behalf of Horticulture Australia Limited, provided data on fenthion residues and the question has been answered on this basis.

1. It is an APVMA requirement that residue trials be undertaken in accordance with OECD Good Laboratory Practice (GLP) principles.

2. The APVMA does not undertake residue trials. The requirement is on the data provider to ensure that the trials are undertaken according to GLP principles.

3. The question about calibration of spray equipment is not clear. Spray equipment should be appropriately calibrated for the specific orchard in which the trial is being conducted. The calibration procedure for the spray equipment used in the trials was detailed in the Agrisearch GLP report.

Question: 62 (continued)

4 & 5. The Agrisearch GLP report was subject to audit according to GLP protocols prior to submission to the APVMA. The GLP report was then subject to an unbiased and independent peer review (evaluation) by the expert pesticide residue scientists at the APVMA.

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Supplementary Budget Estimates November 2013

Agriculture

Question: 63

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA concede that the 'Sum of Fenthion' tests results compose of the following in mg/kg? Fenthion + Fenthion Sulphone + Fenthion Sulphoxide + Fenthion Oxon (Remembering that the definition of the Sum of Fenthion is 'Sum of fenthion, its oxygen analogue and their sulphoxides and sulphones, expressed as fenthion (fat-soluble)').

Answer:

No. This is not the Australian residue definition for fenthion.

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Supplementary Budget Estimates November 2013

Agriculture

Question: 64

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA concede that the GLP trials were conducted in a manner so that the results were expressed as Fenthion + Fenthion Sulphone + Fenthion Sulphoxide + Fenthion Oxon + Fenthion Oxon Sulfone + Fenthion Oxon Sulfoxide?

Answer:

No. The results were reported as the Australian residue definition for fenthion of *Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion.*

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 65

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did the APVMA exclude or reject amounts of HOIG generated data from assessment and decision making because the residue results of Fenthion Oxon Sulfone & Fenthion Oxon Sulfoxide were not present in HOIG results?

Answer:

No. The APVMA made the best use of the Hills Orchard Improvement Group (HOIG) data. See the report available from www.apvma.gov.au/products/review/current/fenthion.php for more details.

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Supplementary Budget Estimates November 2013

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Question: 66

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did both Summerfruit Australia Limited (SAL), on behalf of industry (which was tested by Agrifresh) and HOIG submit their data packages to the APVMA for review in July 2013?

1 Did the APVMA contact Agrifresh on 29th July 2013 via phone, informing the company that the original data package submitted via SAL was not suitable for assessment in any way?

2 Following this, did Agrifresh test 'B' samples to a greater level of accuracy and a second data package was submitted to the APVMA on the 29th of August 2013?

3 Did the APVMA at any stage in the 3 months between July and October contact HOIG to inform them that their data was not, in any way, fully sufficient for assessment and give HOIG the same opportunities that Agrifresh were afforded?

4 Did several teleconferences and email exchanges take place between HOIG and the APVMA in the relevant 3 months, during which the APVMA could have informed HOIG of any data inadequacies?

5 Did the APVMA write to HOIG via email seeking clarifications on specific clerical details on the 23rd of August 2013 and still not take that opportunity to inform HOIG of any data inadequacies?

Answer:

The question references Agrifresh. Agrisearch (not Agrifresh), on behalf of Horticulture Australia Limited, provided data on fenthion residues and the question has been answered on this basis.

The APVMA received data packages from the Hills Orchard Improvement Group (HOIG) on 12 July 2013 and from Summerfruit Australia Limited (SAL) on 8 July 2013.

The APVMA contacted Argrisearch, the laboratory used for the SAL trials, on 29 July 2013 to seek clarification on the Limit of Quantification used in the analytical phase of the study.

Question: 66 (continued)

Agrisearch subsequently reanalysed the data and submitted a revised report on 29 August 2013.

The APVMA contacted the laboratory providing the analytical service for HOIG on 14 August 2013 to seek clarification on the interpretation of the Certificates of Analysis. On 23 August 2013, the laboratory confirmed that they had not reported or analysed to the residue definition. At no time has the laboratory or HOIG presented revised data to the APVMA for consideration.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 67

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

After the APVMA's review of fenthion in 2012, the new MRL's (Maximum Residue Limits) were set at 0.2mg/kg for peaches and apricots and 0.25mg/kg for nectarines and plums. Why has the APVMA set the MRL for peaches and apricots at 0.2mg/kg and the MRL for nectarines and plums at 0.25mg/kg?

Answer:

Maximum residue limits (MRLs) are set at levels which are not likely to be exceeded if a chemical is applied according to approved use patterns. In determining if residues are safe, consideration is given to both the level of residue in the fruit and the levels at which that fruit is consumed. This is then used to determine the dietary exposure risk against the health standards, which are set by the Federal Department of Health.

The different MRLs for peaches/apricots and nectarines/plums relate to a number of factors, including different average fruit sizes and different consumption rates by the general population of each type of fruit. A higher MRL for peaches/apricots (at 0.25mg/kg) would result in exposure estimates above the health standard, whereas for nectarines/plums an MRL of 0.25 mg/kg would result in safe exposure.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 68

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA claim that peaches and apricots treated with fenthion are a higher risk to consumers because the 'furry skin' on these fruits contributes to a slower breakdown of fenthion in natural conditions, compared to nectarines and plums?

Answer:

No. There are a number of factors that can explain the different residue level in peaches/apricots and nectarines/plums.

See the reports available from www.apvma.gov.au/products/review/current/fenthion.php for more detailed information about the residues reported from these two types of fruit.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 69

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Can the APVMA explain why it is safe for 0.25mg/kg of fenthion residue or less to enter a human body by consumption of nectarines or plums, but it is only safe for 0.2mg/kg or less of fenthion residue to enter the human body by consumption of peaches or apricots?

Answer:

Please refer to the answer to Question 67 from the Supplementary Budget Estimates hearing in November 2013.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 70

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

By doing this the APVMA is claiming that 0.2mg/kg of fenthion in a peach or apricot is as equal a risk of harm to 2-6 year olds as 0.25mg/kg in a nectarine or plum. Is it not the fenthion itself or the fruit that provides the risk to the consumer?

Answer:

The APVMA has made no such claim. It is the total amount of fenthion ingested that provides the risk, not the particular kind of fruit. This assessment is dependent on the level of residue in the fruit and the amount consumed within a 24 hour period.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 71

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

It is the With Holding Period (WHP) that should equalise the risk to consumer, not the fruit itself. Hence the WHP of 21 days on peach & apricot and the WHP of 14 days on nectarines and plums that should be the equaliser, not the MRL. Will the APVMA increase the MRL relating to peaches and apricots to 0.25mg/kg? If not, why not??

Answer:

No. Please refer to the answer to Question 67 from the Supplementary Budget Estimates hearing in November 2013 for information about how maximum residue limits are set.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 72

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA have any data suggesting that fenthion consumed from a peach has a slower metabolic or natural breakdown rate in the human body than fenthion consumed from a nectarine?

Answer:

No. Please refer to the answer to Question 67 from the Supplementary Budget Estimates hearing in November 2013 for information about how maximum residue limits are set.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 73

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA have any data to prove that an amount of fenthion consumed from a peach has a greater effect on human health than that same amount of fenthion consumed from a nectarine?

Answer:

No. Please refer to the answer to Question 67 from the Supplementary Budget Estimates hearing in November 2013 for information about how maximum residue limits are set.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 74

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did the first data package tested by Agrifresh and submitted by SAL show many Untreated Control Trees (UTC), that is trees which did not have fenthion applied to them, breaching MRL's set by the APVMA?

Answer:

The question references Agrifresh. Agrisearch (not Agrifresh), on behalf of Horticulture Australia Limited, provided data on fenthion residues and the question has been answered on this basis.

No. Three samples from untreated controls contained trace levels of components of the fenthion residue definition. All of the trace level detections were below the limit of reporting used in HOIG monitoring data of 0.05 mg/kg, and would not have been detected by the HOIG testing or most monitoring programs. The trace level detections were not considered to impact on the validity of the dataset.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 75

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did the second data package, in which 'B' samples were tested by Agrifresh to a far greater degree of accuracy, still show numerous UTC's showing fenthion residues?

Answer:

The question references Agrifresh. Agrisearch (not Agrifresh), on behalf of Horticulture Australia Limited, provided data on fenthion residues and the question has been answered on this basis.

Samples from three sites had trace levels of fenthion. Please refer to the answer to Question 74 from the Supplementary Budget Estimates hearing in November 2013 for more information.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 76

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA believe that UTC's showing residue levels, when there clearly should not be any, seem strange and warrant further investigation?

Answer:

The trace levels for untreated controls were considered in the review of the GLP submission. Please refer to the answer to Question 74 Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority from the Supplementary Budget Estimates hearing in November 2013 for more information.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 77

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA consider Agrifresh's/SAL's submission containing UTC's returning residue levels, despite highly accurate testing, a concern regarding the validity or accuracy of the entire data package?

Answer:

The question references Agrifresh. Agrisearch (not Agrifresh), on behalf of Horticulture Australia Limited, provided data on fenthion residues and the question has been answered on this basis.

Please refer to the answer to Question 74 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 78

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

How did the APVMA treat the data of the UTC's in the Agrifresh data showing residues into when assessing this data for the registration or suspension of fenthion?

Answer:

The question references Agrifresh. Agrisearch (not Agrifresh), on behalf of Horticulture Australia Limited, provided data on fenthion residues and the question has been answered on this basis.

Please refer to the answer to Question 74 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 79

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did the APVMA apply any of the HOIG generated data when deciding to issue a permit for fenthion usage on nectarines and plums during the 2013-14 season containing 1 extra application (now 3 instead of 2), than was allowed last year? If so, which parts of the HOIG data contributed to the allowance on 1 extra application?

Answer:

HOIG generated data was used to support the GLP data set. More information is contained in the *Supplementary Fenthion Residues and Dietary Risk Assessment Report* of October 2013 available from 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: 80

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did the APVMA apply any of the HOIG generated data when deciding that fenthion was unsuitable for usage on peaches & apricots in the permit issued on October 16th 2013?

Answer:

Please refer to the answer to Question 79 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 81

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did the APVMA apply any of the HOIG generated data into when deciding to issue a permit on October 29th 2013 allowing 1 application of fenthion on peaches & apricots with a 21 day With Holding Period?

Answer:

Please refer to the answer to Question 79 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 82

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

If HOIG data was taken into account when issuing the new permit for nectarines and plums; why did the APVMA not issue a permit containing 2 applications with a 10-14 day With Holding Period, as this is at a bare minimum what the HOIG data submitted to the APVMA supported?

Answer:

The APVMA considered all of the data available, including the data generated to GLP standards and the monitoring data submitted by the Hills Orchard Improvement Group (HOIG) and others. On the basis of consideration of the whole dataset for nectarines and plums, a use of two applications with a 10 day withholding period was not considered acceptable. However the dataset supported three applications with a 14 day withholding period.

The assessment is outlined in the *Supplementary Fenthion Residues and Dietary Risk Assessment Report* of October 2013 available from 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: 83

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

The APVMA is often quoted that fenthion is no longer registered for usage against fruit flies in Europe, the USA, Canada & NZ. Does the APVMA concede that there is a large difference between a private company not reregistering its own product and the product being suspended or banned by an independent regulatory authority?

Answer:

There is a difference between a private company not registering its product and a product being suspended by a regulatory authority. However, the outcome is the same in that a product is not registered for use.

The APVMA can confirm its previous statements that fenthion is not registered for use on food producing plants in European Union, USA, Canada or New Zealand.

In Europe the regulatory authority recommended that all plant protection uses be removed in1998 except baits in citrus and olives. In 2004 these remaining uses of fenthion were removed.

In the USA, in 1996 there were no approved uses of fenthion on food plants, and the removal of all uses on mosquitoes and cattle were recommended by the independent regulatory authority in 2001 due to both human health and environmental concerns. This assessment was followed by voluntary withdrawal of products by the company.

The recommendation to withdraw of the use of fenthion on cattle in Canada was based on both environmental and residue concerns. This assessment was followed by voluntary withdrawal of products by the company.

In New Zealand there are no registered fenthion products for use on plants.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 85

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

The APVMA has stated publicly on numerous occasions that it is an independent regulatory body and its decisions cannot be influenced or overturned by the Federal Minister for Agriculture, currently The Honourable Barnaby Joyce. Is the APVMA aware of the Minster's powers under the Ministerial Chamber for Agriculture to overturn decisions, in writing, that are contrary to the National Food Plan?

Answer:

Ministerial direction to the APVMA is limited to that provided for in Section 10 of the *Agricultural and Veterinary Chemicals (Administration) Act* 1992 (the Act). This section, in turn, requires the application of Section 9A of the Act, which provides that where an agreement is in force between the Commonwealth and the states and territories, the APVMA must comply with any policy determined under the Agreement.

Ministerial directions under the Act do not extend to the power to direct the APVMA that a particular decision be made or overturned.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 86

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA concede that is has a poor track record in the Australian Administrative Tribunal, the Federal Court and in having to settling out of court when the regulators decisions are challenged by permit applicants or product manufacturers?

Answer:

No.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 87

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

In several conversations with the Fruit Fly Action Group, the APVMA stresses that it is not a function of the APVMA to assist in finding alternatives when one of their regulatory decisions threatens the survival of a branch of food production. Yet suddenly in the latest media statements issued by the APVMA within the past 2-4 weeks, the regulator speaks of suddenly becoming a compassionate regular contributor in discussions with industry groups and growers in seeking alternative products and systems. Why does the APVMA suddenly see the need to change its role from impartial regulator to compassionate benefactor of industry interested in finding alternatives to fenthion?

Answer:

The APVMA is responsible for ensuring agvet chemicals available in Australia are safe to use. The APVMA is not responsible for investigating alternative treatment methods. Nevertheless, where relevant, the APVMA takes appropriate opportunities to inform industry of other chemicals that are registered for a particular pest or situation.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 88

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

As peaches are one of the fruits that the APVMA isolated for a permit suspension this season, what is the exact mass of peach calculated by the APVMA that needs to be consumed by a child aged between 2-6 years old in the relevant short term time frame for fenthion residue to pose a health risk?

Answer:

Based on the currently available evidence, 305 g of fresh peach (the equivalent of 2 peaches), with a Maximum Residue Level of 0.2mg/kg can be safely consumed over a 24 hour period by a 5 year old child.

Residue levels above 0.2 mg/kg total fenthion or amounts of peach above 305 g would result in the consumption of fenthion at levels above the short-term (24 hour) public health standard for fenthion that was set by the Federal Department of Health.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 89

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

As apricots are one of the fruits that the APVMA isolated for a permit suspension this season, what is the exact volume of apricot that needs to be consumed by a child aged between 2-6 years old in the relevant short term time frame for fenthion residue to pose a health risk?

Answer:

Based on the currently available evidence, 305 g of fresh apricots, with a Maximum Residue Level of 0.2mg/kg can be safely consumed over a 24 hour period by a 5 year old child.

Residue levels above 0.2 mg/kg total fenthion or amounts of apricots above 305 g would result in the consumption of fenthion at levels above the short-term (24 hour) public health standard for fenthion that was set by the Federal Department of Health.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 90

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

According to the 2007 Australian National Children's Nutrition and Physical Activity Survey, (http://www.health.gov.au/internet/main/publishing.nsf/Content/8F4516D5FAC0700ACA257BF0001E0109/$File/childrens-nut-phys-survey.pdf) the highest average daily intake for any child, boy or girl, between 2-6 years old is just 185.8g (page 11). This figure does not just constitute fresh fruit, it also incorporates fruit juices, tinned fruits and any processed/prefabricated fruit based product. Any reasonable person should expect that the exact figure of fresh fruit consumption in isolation, must be lower than 185.8g. Does the APVMA, after hearing these figures, concede that they have exaggerated the true potential risk of fenthion residue to any child in the 2-6 year old age category?

Answer:

Food Standards Australia New Zealand (FSANZ) is responsible for providing food consumption data to the APVMA for use in dietary exposure assessments. Dietary exposure assessments undertaken by the APVMA are peer reviewed by expert scientists at FSANZ before maximum residue limits are varied in the Australia New Zealand Food Standards Code.

The fresh fruit consumption figure of 185.8g quoted in the question is not appropriate for use in analysis of short-term dietary exposure undertaken by the APVMA in assessing an application for a particular pattern of use for a pesticide. This figure is the mean daily consumption of Fruit Products and dishes for 2-3 year old boys referenced in Table 4 of the *Main Findings of the 2007 Australian National Children's Nutrition and Physical Activity Survey* (see www.health.gov.au/internet/main/publishing.nsf/Content/phd-nutrition-childrens-survey). The figure is an aggregated average consumption figure. The APVMA considers the short-term dietary exposure based on the residues resulting from a proposed pattern on individual fruit types and the appropriate consumption figure for the specific fruit type.

Any questions about the food consumption data should be directed to FSANZ.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 91

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

According to the Federal Department of Health (http://www.healthyactive.gov.au/internet/healthyactive/publishing.nsf/Content/fact

1) one serve of fruit is calculated to be one of the following, or an equivalent;

- 1 medium piece, eg, apple, banana, orange, pear
- 2 small pieces, eg, apricots, kiwi fruit, plums
- 1 cup diced pieces or canned fruit
- 1/2 cup juice
- dried fruit, eg, 4 dried apricot halves, 1 1/2 tablespoons sultanas.

On top of this information, the Government's 'Go for 2&5 program', it is recommended that adults should consume 2 serves of fruit and 5 serves of vegetables per day. The youngest age group mentioned in the 'Go for 2 & 5' program are children in the 4-7 year old category, the advice given is for them to only eat 1 serve of fruit & 2 serves of vegetables. Given the information provided above and the answer provided by the APVMA regarding the volume of peach or apricot required to pose a dietary risk, does the regulator now concede that its claims of risk to children in the 2-6 year old age category have been exaggerated?

Answer:

No.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 92

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Has the APVMA conducted a statistical analysis of the risk, in percentile terms, to calculate the exact chance that a child eating the volume of fruit required by the APVMA, becoming ill?

Answer:

No. Public health standards are set by the Federal Department of Health. Short-term dietary exposure is determined based on international standards which the APVMA applies under an agreed protocol with Food Standards Australia New Zealand (FSANZ). All residues present in food as the result of approved uses of pesticides must be safe for any consumer. Statistical analysis that derives a percentile or probability of a child eating the volume of fruit required to cause harm is not considered in pesticide risk assessment in Australia.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 94

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

Topic: Fenthion

Proof Hansard page: Written

Senator Back asked:

Does the APVMA generate any of its own data in regards to the various requirements of making calculations during the risk assessment process?

Answer:

No. The APVMA does not generate residue data or determine public health standards. Dietary exposure assessment methods used are agreed by the APVMA and Food Standards Australia New Zealand (FSANZ), and are in accordance with international standards.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 95

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Is it fair to say that the assessment on the risks of illness to a child in the 2-6 year old age bracket is based on the APVMA collecting a series of data generated through external sources and organisations and then crunching them through a mathematical algorithm which then spits out a rigid and inflexible response? If this is the case, why has the APVMA flip-flopped on fenthion regulation 4 times between Sept 2012-Oct2013?

Answer:

The APVMA assesses the data that is submitted to it by product registrants and by industry bodies or is published available data. The assessment protocol agreed to by the APVMA and Food Standards Australia New Zealand (FSANZ) gives a clear and definite answer as to whether the dietary exposure for a particular pattern of use meets the public health standard or not.

Please refer to the answer to Question 54 Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority from the Supplementary Budget Estimates hearing in November 2013 for more information.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 96

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA take into account any real world data, for example, that fenthion has been used worldwide for over 50 years and there has not been one documented case of illness from any age bracket from the consumption of fresh produce in that period?

Answer:

Please refer to the answer to Question 59 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 97

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

As a scientific organisation, the APVMA would be familiar with the oft quoted scientific principle that 'Observation always trumps prediction'. Would the APVMA, being a scientifically-based body, agree that physical evidence should have a greater weighting than a mathematical prediction when making decisions that affect every Australian resident?

Answer:

Please refer to the answer to Question 54 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 99

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

In its role as a public safety regulator relating to chemical residue risk and as the current situation lies before us, would the APVMA consider locally grown produce or imported produce to be the greater risk to the 2-6 year old category?

Answer:

Please refer to the answer to Question 98 from the Supplementary Budget Estimates hearing in November 2013 for more information.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 101

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

If the document was peer reviewed, does the APVMA have any ongoing ties or relationship with the body/bodies that peer reviewed the document? If the document was not peer reviewed, why was it not?

Answer:

Please refer to the answer to Question 100 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 102

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Will the APVMA submit their latest Residues and Dietary Exposure Assessment for a peer review by a body with which they have had no previous contact?

Answer:

Please refer to the answer to Question 100 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 103

Division/Agency: Agricultural Productivity Division/Australian Pesticide Veterinary Medicine Authority

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

The APVMA promised HOIG that they would have 2 weeks to review and respond to the APVMA's latest Residues and Dietary Exposure Assessment prior to it being made public. Why did the APVMA only give HOIG 1 hour's notice via teleconference before making the assessment public on its website?

Answer:

The APVMA received initial data packages in July 2013 and revised data was received at the end of August 2013. Analysis of all of the information required some time to complete to ensure it was comprehensive. The analysis of the data took a number of weeks. Noting the 2012 permit was due to expire at the end of October 2013, the APVMA published the assessment without further consultation to avoid any further delay.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 104

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Given the events of the previous year in which the APVMA was under immense public scrutiny, did the APVMA go back on its promise of 2 weeks' notice to avoid the same public pressures?

Answer:

Please refer to the answer to Question 103 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 105

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Did the APVMA act in a tactical manner by only giving HOIG 1 hour's notice of public posting so that HOIG would be unable to mount a defence?

Answer:

Please refer to the answer to Question 103 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 106

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

In 2012 the APVMA waited until 6 weeks before the commencement of harvest before announcing the suspension of fenthion for usage on stone fruit and in 2013 the APVMA acted to suspend fenthion for usage on peaches and apricots only 3 weeks before the commencement of harvest. On both occasions, why has the APVMA waited until the eve of harvest before throwing the stone fruit industry into turmoil by removing fenthion from usage against fruit fly?

Answer:

On both occasions the timing of the decision was dependent on the timing of the completion of the residues assessments.

This in turn is dependent on when relevant data is submitted, the amount of data and the time required to assess it. In 2013 residues data was submitted by three industry groups in July and revised data was submitted in August 2013.

The analysis of the data took a number of weeks. Given the 2012 permit was due to expire at the end of October 2013, the APVMA published the assessment and decision as soon as was practicable.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 108

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

Topic: Fenthion

Proof Hansard page: Written

Senator BACK asked:

Does the APVMA concede that in future it would be fair to industry to consider the timing of suspensions/bans so that growers have time to implement other strategies or can decide whether they wish to commit 11 months' work and tens-to-hundreds of thousands of dollars to raising their crops to point of harvest?

Answer:

Please refer to the answer to Question 106 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 112

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

Topic: Restrictions reduced to allow one spray

Proof Hansard page: Written

Senator STERLE asked:

Why were the restrictions reduced to allow one spray between 29 October and the end of April (2014?)?

Answer:

Please refer to the answer to Question 57 from the Supplementary Budget Estimates hearing in November 2013 for more information.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates November 2013

Agriculture

Question: 113

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

Topic: Exploration for use of other pesticides

Proof Hansard page: Written

Senator STERLE asked:

Are any other pesticide (or other) treatments being explored for use (or expanded use) in Australia?

Answer:

The APVMA is aware that state and territory governments, Horticulture Australia Limited, industry bodies and commercial companies have been conducting research into a range of alternate options for the control of fruit flies across a wide range of food crops in Australia. The APVMA itself does not conduct research into alternate treatments and it is beyond the scope of the APVMA's legislative responsibilities.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 115

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

Topic: Minister to follow advice of the APVMA

Proof Hansard page: Written

Senator STERLE asked:

Is it standard practice for the Minister to follow the advice of the APVMA in such circumstances?

Answer:

Please refer to the answer to Question 114 from the Supplementary Budget Estimates hearing in November 2013.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 116

Division/Agency: Agricultural Productivity Division/Australian Pesticide Veterinary Medicine Authority

Topic: Atrazine/Simazine

Proof Hansard page: Written

Senator RHIANNON asked:

1. What testing has been done regarding pesticide runoff from forestry plantations under RFAs? Particularly atrazine runoff?
    a) What communities have been impacted? What were the results?
    b) What information is available regarding rumoured cancer clusters in SE NSW associated with plantation development?
        i. Have any samples been taken; if so when, where and in what quantity?
2. The Victorian EPA recently published a report looking at pesticide detections in two subcatchments of the Latrobe River. Traces of simazine were found some 9 years after it was last used in the catchment at Middle Creek. Trans-chlordane was also detected almost 20 years since last used in forestry operations.
    a) How widely are these chemicals still used in forestry operations? In which states has the use thereof been discontinued? Does the FSC allow the use of these chemicals?
3. The longest event of pesticide run-off data in Victoria seems to have been associated with the pine plantation herbicide hexazinone, from an FSC certified plantation – how widely used is this chemical?
4. Simazine was placed on the APVMA Priority Candidate Review List as a priority 2 chemical in the mid 1990s. Where is this review up to? What are the results? What are other comparable countries?
5. Recognising that responsibility for water supplies lies with various agencies including local government, what information is available indicating which communities, both via town supplies or drawing directly from water sources downstream from plantations and intensive agriculture?

Question: 116 (continued)

Answer:

1. The Australian Pesticide Veterinary Medicine Authority (APVMA) is not aware of the matters referred to in this question.

2. There are no registered products containing chlordane. Registered products containing simazine are approved for use in forestry operation in all states. The APVMA does not hold information regarding the extent of use of simazine products nor is aware of policy decisions of FSC regarding recommended chemicals for use in forestry operations.

3. There are approximately 20 registered products containing hexazinone approved for use in pine plantations. The APVMA does not hold information regarding the extent of use of hexazinone.

4. The APVMA has not commenced a review of simazine. Simazine is registered for use in the US in many situations including tree plantations. The USEPA reviewed simazine in 2006 subsequently supporting continued registration subject to additional restrictions including prohibition of granular formulations and limits to application rates.

5. The matters raised in this question are beyond the scope of the APVMA's responsibilities.