Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 55

Division/Agency: APD – Agricultural Productivity Division/APVMA – Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural chemicals
Proof Hansard page: 102

Senator COLBECK asked:

Senator COLBECK: So is the report that was sponsored by Earth Open Source a new report or an old report?
Dr Bennet-Jenkins: I know the report that you are talking about, but I am not sure whether I know when it was actually published, so I will take that on notice. We can certainly get back to you in terms of what parts of that report we have examined. It has not had any impact in terms of the regulatory status of glyphosate from our perspective at this stage.

Answer:

The report *Roundup and birth defects: Is the public being kept in the dark?* was published in June 2011 by Earth Open Source on behalf of a group of international scientists. It examined the basis for the European Commission's original approval of glyphosate in 1998.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 56

Division/Agency: APD – Agricultural Productivity Division/APVMA – Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: 104

Senator Waters asked:

Dr Bennet-Jenkins: Diuron is a chemical that has been registered for a number of years. I do not believe the current use patterns are as high as 75 kilos.
Senator WATERS: I certainly hope not.
Dr Bennet-Jenkins: I am not quite sure. We can take on notice what the highest use rate is if you would like to know what that is.
Senator WATERS: Thank you. And also the highest rate that you have approved, as well as the actual current rate.

Answer:

The highest currently approved label rate is 144 kg product/ha. This is equivalent to 72 kg of diuron/ha. This is also the actual current rate for use of diuron in channels and drains only.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 169

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

Senator COLBECK asked:

1. QON 30 May 2011 indicated that a Bill was being drafted for consultation with states and territories and other stakeholders. What is the status of this Bill?
2. Who are the "other stakeholders"?
3. Are public meetings being held as part of the consultation and if so, what is the schedule for these meetings?
4. Will there be any increase in costs to farmers or registration costs due to the reform of the APVMA?
5. Will these reviews consider the recurring issue of lag periods between the outbreak of new pests and diseases and the ability for producers / land managers to deal with it?

Answer:

1-5 The Government has rereleased exposure draft legislation to reform the registration process.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 170

Division/Agency: APD/APVMA – Agricultural Productivity Division / Australian Pesticides and Veterinary Medicines Authority
Topic: Sunland hatchery
Proof Hansard page: Written

Senator COLBECK asked:

The Noosa News 7 October 2011 reported that results of tests in June "did not prove conclusive evidence to warrant a ban on the use of agri-chemicals on macadamia farm next door." One of the task force vets has weighed in and is "imploring the Federal Government to intervene"

1. What requests has the Minister had with regard to intervention on this issue?

2. In response to QON 31, May 2011, the APVMA advised that information was being assessed and had not yet determined whether pesticides were involved and/or whether regulatory action was warranted. Please provide an update on the status of this assessment.

Answer:

1. The Minister has no power to intervene nor can the minister direct the APVMA to reconsider the registration of a chemical, consistent with the legislative framework introduced by the Howard Government.

2. Question on Notice 31 relates to the additional adverse experience reports received by the APVMA. The APVMA previously advised that it had received and was assessing 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 assessments have now been finalised and their status has been published on the APVMA website in 'Update on the APVMA's response to the Noosa taskforce report' on 13 October 2011 under the headings 'Adverse experience reports involving other animals kept on the fish farm' and 'Adverse experience reports involving human health'. These documents are available at www.apvma.gov.au/news_media/news/2011/2011-10-13_noosa_taskforce_report.php

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 171

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Product review process
Proof Hansard page: Written

Senator COLBECK asked:

1. How does the Department intend to address the inadequate data protection for data submitted to the APVMA for products under review?
2. How does the Department intend to address the issue that APVMA is precluded from considering the environmental impacts associated with removal of a product. For example, if removal of a product is likely to result in mechanical weed control (tillage) the environmental impacts of topsoil erosion, sediment loss and greenhouse emissions are not considered?
3. The risk assessments conducted by the APVMA analyse the risks associated with 'worst case' scenarios that are unrealistic and do not reflect the genuine risk associated with use. Does this approach over estimate true risk and result in excessive restrictions on use by farmers?

Answer:

1. Details of proposed changes to data protection provisions to encourage submission of appropriate data at relevant stages of the assessment, re-registration and review processes will be included in an exposure Bill.

2 In assessing agricultural and veterinary (agvet) chemicals, whether to place them on the market or to remove them, the APVMA is required to assess impacts on human health, the environment and trade. This is because of the legislative framework established by the Howard government.

3. No. The APVMA follows international best practice in the conduct of risk assessments.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 172

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Diuron
Proof Hansard page: Written

Senator COLBECK asked:

1. What application rates were used in the risk assessment?
2. Why were the interim report results so different from the final findings
3. How could companies know they need to provide data into the review of Diuron when the interim findings were for rates of 900 grams which many thought were acceptable and did not need to provide data, yet the final report finds a much lower rate is acceptable?
4. Do the monitoring levels differentiate between free Diuron in water as opposed to that bound to sediment?
5. What evidence is there that Diuron bound to sediment has different impact on plants and algae and has this been taken into account?
6. Table C22 on page 49 indicates that for sugarcane, the risk assessment application rate was between 1.8 and 3.6 kg/ha. However Canegrowers have submitted additional data to the APVMA to suggest that current practices are that application rated are well below 1.8kg/ha. Have these current rates been taken into consideration?
7. The risk assessment assumed that birds obtained all their food from the area treated with diuron (paragraph 1.13.1, page 51) and that contaminated food is not avoided. Is this realistic?
8. Herbicide treatment will generally only occur once, or maybe twice each year – and dietary exposures for the remainder of the year would be much less and so would not the impact on the diet also be much less?
9. The environmental risk assessment considers that there is an unacceptable risk to aquatic plants and algae in primary streams (page 56-57). What is the definition of a primary stream?
10. What is the definition of a secondary stream?
11. The 95th percentile is used for preserving pristine natural environments, streams in agricultural systems are regularly highly modified after decades of agriculture and are far from the state that they would have been in prior to agriculture commencing why wouldn't a 90th percentile protection level be acceptable?
12. If the 90th percentile was adopted as the appropriate protection level, what rates would be acceptable for Diuron application?
13. The risk assessment recognises that for barley and wheat applications, the risk to algae and aquatic plants in primary streams remains unacceptable (p57). The report also acknowledges that these streams are often dry. How can there be a risk to aquatic plants and algae if the streams are dry?

Question 172 (continued)

14. The Queensland government has initiated additional controls including setbacks from water courses, maximum annual application rates and other use restrictions. Have these been taken into account?
15. These restrictions could have an impact on the risks to aquatic plant life could they not? If so, why not take the results of these additional restrictions into account?
16. Will the APVMA review the runoff concentrations from the new restrictions before finalising their position?
17. Which area of the Department of Sustainability, Environment, Water, Population and Communities is responsible for providing the advice to the APVMA on the environmental impacts of Diuron?

Answer:

1. The diuron risk assessment used 4 representative rates - 0.45 kg active/ha, 0.9 kg active/ha, 1.8 kg active/ha and 3.6 kg active/ha. These were chosen to represent the range of registered broadacre uses.

2. While the interim report on diuron focussed primarily on sugarcane, a more crop-specific assessment for broadacre agriculture was undertaken for the final assessment. The assessment was also substantially revised and utilised revised ecotoxicity endpoints, enhanced modelling and use of new monitoring data.

3. At the commencement of a review all registrants are required by legislation to provide all relevant data that they are aware of. Once the assessment of that information is completed it is published as a preliminary review findings report (interim report) and registrants and other stakeholders are invited to provide any further information that may have an impact on the review findings. If new data provided in response to an interim report substantially changes the review outcome from that proposed in the interim report, the APVMA advises all registrants and stakeholders ahead of making a decision, as is the case for diuron.

4. Yes, current monitoring levels are able to differentiate between free diuron in the water column and diuron bound to sediment.

5. There is no evidence that diuron bound to sediment has a different impact on plants and algae.

6. Yes.

7. The risk assessment is based on ‘worst case scenario’ as there was limited information on what might be a ‘realistic’ case. However, further information provided in response to release of the 2011 report is expected to enable the APVMA, in consultation with Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), to refine the assessment for birds.

Question: 172 (continued)

8. Yes.

9. Primary streams are smaller creeks or brooks which are often found closest to farm lands and receive the first 'edge of field' water from runoff events.

10. Secondary streams include rivers and larger streams receiving inflows from primary streams.

11. Lower percentiles can be applied to different ecosystem conditions. While this can be adopted for specific water bodies/catchments, it is not practical to do so for a national assessment.

12. Acceptable rates for a 90th percentile protection level would be 190g active/ha for protection of primary streams or 1.3 kg active/ha for the protection of secondary streams.

13. The risk assessment looked at a nationwide, worst case scenario (ie assuming active streams at all times). This is in line with current environmental assessment methodology. The information received following the release of the 2011 report is expected to enable APVMA/DSEWPaC to refine the assessment for uses that occur in drier areas of Australia.

14. Yes, the 2011 report has noted that such measures are in place. However, at the time of the assessment the scientific basis for these recommendations was not known. There was no monitoring information available that had measured the effectiveness of these programs in reducing environmental risks associated with diuron. Initial results have now been provided and will be considered by the APVMA.

15. Yes. The restrictions were designed to reduce diuron runoff and impact on aquatic systems. We have received the data from monitoring programs associated with these restrictions which will help determine whether such restrictions have been effective. This information will be considered by the APVMA.

16. Yes, the APVMA will consider the monitoring data before finalising the regulatory outcome for the review.

17. The Chemical Assessment Section of the Environment Protection Branch.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 209

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Diuron
Proof Hansard page: Written

Senator HEFFERNAN asked:

1. Is the APVMA considering the fact that farmers are now only using 1.8 to 1.3kg/ha of diuron for weed and grass control when making their considerations?
2. What research, information and advice is the APVMA relying on in making a decision on the banning of diuron?
3. With no affordable replacement for diuron currently on the market, are APVMA taking into consideration that farmers will have to return to old farming practices for weed and grass control in their crops, therefore raising the amount of erosion and sediment run-off into our waterways?
4. Would the APVMA consider a longer phasing out period for diuron to 2020, to give time for new products to be developed and tested for the sugar industry?

Answer:

1. Yes, Please see answer to Question 172

2. The APVMA utilised data submitted by the registrants, research and information submitted by stakeholders such as state and territory government agencies or research institutions, publicly available scientific literature, Australian and international monitoring data as well as international regulatory assessments of diuron up until 2009. More recent information not previously considered has now been received and will be considered in the assessment.

3. The APVMA legislation, implemented by the Howard Government, does not permit the APVMA to consider either the cost or the environmental risk that alternatives would pose if diuron were to be removed.

4. No. The APVMA legislation does not have provision for a phase-out of more than 2 years.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 210

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Industry programs
Proof Hansard page: Written

Senator HEFFERNAN asked:

Is the APVMA taking into account that industry programs, like Reef Rescue worth $200million, have not yet been fully realised, no new testing of waterways since introduction of packages.

Answer:

Yes. The APVMA has received the 2009–10 and 2010–11 monitoring results from these programs. This information will be taken into consideration in the final decision for diuron.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 211

Division/Agency: APD/APVMA – Agricultural Productivity Division / Agricultural Pesticides and Veterinary Medicines Authority
Topic: Introduction of new chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

What is the APVMA and Federal Government doing to promote the introduction of new chemicals into the market place?

Answer:

As part of the Better Regulation reforms of the Agricultural Pesticides and Veterinary Medicines Authority (APVMA), the Australian Government is promoting the development of more modern and safe chemicals through:

- improving existing data protection and removing the disincentive for companies to invest in cutting edge technologies
- cutting red tape by enhancing the APVMA's business and operational functions, particularly for low risk products
- improving assessment processes, to ensure that they are is easier to understand, provide more predictable outcomes and are more cost effective to administer.

Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2011

Agriculture, Fisheries and Forestry

Question: 224

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Diuron
Proof Hansard page: Written

Senator WATERS asked:

With regard to APVMA's decision making framework regarding whether or not to reduce or ban usage of diuron –

a. Can APVMA take into account the fact that current best practice diuron usage (according to Cane growers) is 900g/ha/application, and that 160g/ha/application may not be able to do the job required of it? Is that it wouldn't be effective, and could potentially encourage weed resilience?
b. Is APVMA obliged to ban usage all together if an effective herbicide is way above environmentally safe levels?
c. Where APVMA is considering requiring lower application rates of diuron, does APVMA assess and / or consider the difficulties states and territories may have in ensuring compliance with that lower application rate on the ground? Ie does APVMA consider the likely practical environmental outcomes of the regulatory change, or does it simply assume full compliance with the new requirements?

Answer:

a. Yes, the APVMA will need to be satisfied that any lower use rates that it proposed to permit are effective.

b. No.

c. Yes, the APVMA does consider whether such label instructions would be enforceable and able to be complied with, through consultation with states and territories.

Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates 17 Oct 2011

Agriculture, Fisheries and Forestry Portfolio

Question: 225

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

Senator HEFFERNAN asked:

1. How does APVMA assess the amount of off-site vapour drift which occurs after completion of spraying and more specifically, what audit and compliance monitoring does the APVMA undertake and/or include in their assessment requirements for the continued registration of AGVET chemicals and their reviews?
2. What environmental monitoring data requirements are included in the registration, reviews and assessments of AGVET chemicals, and with regard to trichlorfon specifically – what percentage of this chemically breaks down into dichlorvos in a real life situation, such as spraying of a macadamia orchard?
3. What label controls has the APVMA put in place to avoid off-site movement of vapour and specifically for how long after trichlorfon application is it unsafe for pregnant orchard workers and their toddlers to be exposed to trichlorfon and dichlorvos?
4. If you do not know the answer to questions 2 and 3 with regard to trichlorfon, how do you assess the actual risk of harm to humans, animals and fish, especially with regard to pregnant women?
5. Does the APVMA consider that an unborn foetus has a different susceptibility to AGVET chemicals than an adult, and specifically, how are the effects of chemical mixtures and endocrine disrupting chemical mixtures allowed for with regard to the protection of a foetus?
6. How does APVMA ensure that there is protection to developing foeti?
7. What laboratories in Australia are able to measure AGVET chemicals in human blood for those citizens that have been adversely affected by exposures during spraying in both agricultural and urban environments?
8. What advice and support is provided to the medical profession by the APVMA when patients present to them with an AGVET chemical exposure and are suffering adverse reactions?

Answer:

1. The amount of off-site vapour drift is assessed where there is scientific evidence that this is likely to or does occur at significant levels. This assessment may occur during product registration or during a ‘reconsideration’. The risks of vapour accumulation are also considered where a volatile chemical is used in a confined space such as the use of dichlorvos in grain storage.

Question: 225 (continued)

The APVMA's audit and compliance role is summarised in a fact sheet at www.apvma.gov.au/publications/fact_sheets/docs/compliance.pdf. The APVMA monitors and enforces compliance of agvet products with the Agvet Code up to and including the point of retail sale. Compliance with respect to application of an agricultural chemical product according to the label instructions is primarily a matter for the states and territories which have control-of-use powers to ensure continued compliance with the conditions of registration.

The APVMA may seek advice or information arising from state and territory compliance activities and concerns as part of the chemical review process.

2. A requirement for monitoring may be included as part of a research permit, with results provided for the assessment during a registration application. Monitoring studies have been required during chemical reviews.

   A published study looking at volatilisation of trichlorfon from grass, found that less than 12 per cent of applied insecticide was lost as measured volatile residues (including dichlorvos) during the sampling period [Crop Science 36(6): 1446-1454 (1996)].

3. The APVMA does not require any specific label statement in relation to the risk of off-site movement of vapour following the use of trichlorfon. Current label directions for trichlorfon products include 'Do Not allow entry into treated areas until the spray deposits have dried'. This is protective of all population groups, including pregnant workers and toddlers.

4. See answers 2 and 3.

5. The APVMA considers that the developing foetus is assumed to be more sensitive than adults because any interference with normal biological processes or conditions may be potentially disruptive of development. Additionally, the foetus does not have fully developed excretory or detoxification mechanisms present in adult animals. Therefore, reproductive and development testing of pesticides is a requirement before they can be approved for use.

   The toxicity testing of mixtures is an issue under active consideration by scientists and regulators worldwide. Effects of chemical mixtures are assessed if there is evidence that exposure to a mixture of chemicals at significant levels is likely to occur in a developing foetus. Standard toxicological tests in laboratory animals include investigation of a wide range of endpoints, from gross observations (changes in the behaviour, appearance and bodyweight) to changes in the activity of a wide range of metabolic enzymes and levels of various metabolites and ions, as well as changes in histopathological appearance of all major organs and tissues. Such studies will detect the effects of test chemicals, regardless of whether they are acting through an endocrine mechanism or some other mechanism.

Question: 225 (continued)

6. See responses to Question 4 and 5. The APVMA requires appropriate data to assess the risk at registration.

7. The APVMA does not keep a register of such laboratories.

8. The APVMA is a regulatory authority. It is not intended to be a primary source of toxicology advice to the medical profession. Poison Information Centres and clinical toxicology departments around Australia have the knowledge and resources to treat cases of poisoning by chemicals and are aware of those chemicals which have specific effects for which specific antidotes are available. For other chemicals, clinical toxicologists will use general symptomatic treatment of overdoses.

   The APVMA provides resources on its website, including the Public Chemical Registration Information System listing of products and their labels, the active constituent(s) they contain, the concentration of the active constituent(s), and the presence and concentration of any other product constituents that are classified as a poison requiring poisons scheduling. Product labels will also contain information such as warnings and safety directions, what to do in an event of accidental exposure or where exposure for certain people such as pregnant women is contraindicated.