Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2012

Agriculture, Fisheries and Forestry

Question: 125

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

Senator EDWARDS asked:

1. Agricultural spray drift has been a big issue in the South Australian wine regions amongst grape growers. I understand that regulation of chemical use is primarily the domain of the states but is the APVMA doing anything about this issue?
2. Are there any talks around harmonising regulation between the states?
3. Has the APVMA had any discussions with any of the States or Territories about agricultural spray drift, within CoAG or in any other forum?

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority determines instructions (either at time of registration or via a review) in relation to spray drift management, which can include no-spray zones for agricultural chemical products labelled for use outdoors, that can be applied as sprays or dusts. The instructions are placed on the product's label.

2. Yes, there have been talks around harmonising regulation of chemical use as part of the Council of Australian Governments' reforms to the regulation of chemicals and plastics.

3. Yes.

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Agriculture, Fisheries and Forestry

Question: 126

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

Senator EDWARDS asked:

1. Is the APVMA aware of the recent collapse of SP Exports (tomato grower) in Queensland?
2. Is the APVMA aware that SP Exports was negatively impacted by two incidences of chemical spray drift?
3. Queensland does not have requirements for chemical users to have licences, permits or keep records of when chemicals have been sprayed (unless they are a commercial operator). Does this not highlight the need for national regulations relating to the application of agricultural chemical use?

Answer:

1. Yes.

2. No, the Australian Pesticides and Veterinary Medicines Authority has no record of an adverse experience report being lodged by SP Exports.

3. Yes, this does highlight a need for national regulations of agricultural chemical use which are being considered as part of the Council of Australian Governments reforms to chemicals and plastics regulation.

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Agriculture, Fisheries and Forestry

Question: 136

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 no-use period currently prescribed in the diuron suspension permit likely to appear on the new label conditions?
2. What scientific data supported the no-use period of 5 December 2011 to 31 March 2012 that appears on the diuron suspension permit?
3. What information and data would APVMA require to ensure a no-use period does not appear on the new label conditions for diuron?
4. The one week period of notice given to sugarcane growers and end-users of diuron provided little time for them to schedule the application of diuron as part of their weed management strategy that meets the appropriate crop cycle and weather conditions. What wasn't more notice provided?
5. Spot spraying which targets specific grass problem spots on farm, is an effective weed management tool used in integrated weed management systems in the sugarcane industry. Why aren't growers able to use this effective tool under the suspension permit and is this likely to continue on the new label conditions?
6. CANEGROWERS in their submission on diuron to the APVMA have demonstrated that diuron at a rate of 1.8kg active per hectare per year is industry best practice. This rate is half the label rate and is used by more than 80% of the industry. Is the rate of 1.8kg likely to remain on the new label conditions?

Answer:

1. The long-term use of diuron, including new label instructions, has not yet been decided.

2. The no-use period was based on the results of a modelling study, included in the environment report published in July 2011. The results showed that a theoretical reduction in diuron runoff (by up to 73 per cent) could be achieved in high rainfall areas if use was not permitted during the 'wet season'.

3. The type of information or data the Australian Pesticides and Veterinary Medicines Authority (APVMA) would need is information/data that shows that continued use of diuron during or following high-rainfall events does not result in run-off containing diuron at levels above the safety thresholds for aquatic systems.

Question: 136 (continued)

4. Consultation with industry on the APVMA's review of the use of diuron commenced on July 2011. Industry was asked to provide submissions responding to the environment report published in July 2011, and the submission time period was extended 30 September 2011 at the request of industry. In addition, meetings were held with major product registrants and canegrowers to discuss the possible directions of the review, including the introduction of such a restriction prior to the formal notice being issued on 28 November 2011.

5. The APVMA had insufficient information to be satisfied diuron levels in run-off resulting from spot-spraying in sugarcane during high rainfall periods did not pose a risk to aquatic environments. Until the assessment of additional information is complete and a report from the Department of Sustainability, Environment, Water, Population and Communities has been considered by the APVMA, the outcomes of the diuron review including spot spraying in sugarcane cannot be formulated.

6. Until all of the new information is considered, the outcomes of the diuron review, including application rates in sugarcane, cannot be formulated.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 183

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

Senator COLBECK asked:

With regard to the Better Regulation reforms, given the current policy is to recover 60% of the assessment costs through a levy on sales, what efforts have been taken to engage the end users in the review – ie farmers?

Answer:

The end users of agricultural and veterinary chemicals (including farmers, fishers, foresters, veterinarians and the wider community) were engaged by the department during the development of the Better Regulation of Agricultural and Veterinary Chemicals reforms. The department met with several peak agrifood industry bodies as well as community, environment and chemical industry stakeholder groups at the discussion paper stage and again immediately following the release of a draft Bill in November 2011.

In February 2012 a series of consultation meetings focussing on the exposure draft Bill were held around the country. The department advertised this series of meetings on its homepage as well as by contacting those who had made submissions in response to the 2010 discussion paper and/or had flagged interest in agvet reform issues via the Council of Australian Governments' (COAG) single national framework reform process.

Attendees included a range of peak bodies representing agrifood industry end users of agricultural and veterinary chemicals, as well as stakeholder organisations representing commercial application (eg veterinarians, aerial agriculture and pest controllers) as well as several individual primary producers. The bodies participating that represented primary producers included:

- National Farmers Federation Ltd
- Cattle Council of Australia
- Grain Producers Australia Ltd
- Cotton Australia
- Australian Pork Limited
- Apple and Pear Australia Limited
- National Garden Industry Association
- Australian Southern Bluefin Tuna Industry Association
- Australian Mango Industry Association Ltd

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- Australian Olive Association Ltd
- Australian Rubus Growers Association Inc
- Horticulture Australia Ltd
- Dairy Australia Ltd
- Mohair Australia Ltd
- GrainCorp
- Queensland Fruit and Vegetable Growers Ltd (Growcom)
- AgForce Queensland
- NSW Farmers' Association
- Victorian Farmers Federation
- Tasmanian Agricultural Productivity Group Ltd
- Tasmanian Farmers & Graziers Association Ltd
- Poppy Growers Tasmania Inc
- Pastoralists and Graziers Association of Western Australia Inc
- Fruit West.

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Agriculture, Fisheries and Forestry

Question: 184

Division/Agency: APD/APVMA – Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Quarter 2 2011/12 Data Provided
Proof Hansard page: Written

Senator COLBECK asked:

The efficiency data provided by the APVMA for Quarter 2 2011/12 shows some classes of application are only being processed on time 37% of the time. Why is this and where are the blockages in the process?

Answer:

The Australian Pesticides and Veterinary Medicines Authority's (APVMA) performance against statutory timeframes is less than expected for some application categories. The most common reason applications are not finalised within statutory timeframes is because the applicant has been required to correct the application several times. This can involve correction or clarification of information or the provision of new data and information and often results in assessment processes by the APVMA and other relevant agencies being repeated.

The Better Regulation of Agricultural and Veterinary Chemicals reforms aim to reduce the overall time taken to process registrations and provide better predictability for applicants. The current 'stop the clock' system will be replaced with an elapsed time approach. Applicants will be supported to provide better quality applications that do not need to be corrected or supplemented. In addition the Department of Agriculture, Fisheries and Forestry is working with the APVMA, the Department for the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC) and the Department of Health and Ageing (DoHA) to improve the administrative efficiencies in the way in which the APVMA seeks and receives advice from SEWPaC and DoHA.

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Agriculture, Fisheries and Forestry

Question: 185

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

Senator COLBECK asked:

1. Has the Department assessed in real dollar terms the costs and benefits to the registration system from implementation of the proposed reforms? What are they?
2. The process appears to be significantly behind schedule now, when is the Government planning to introduce the final version of the bill into parliament and surely the proposed operation date of the new system of July 1 this year is no longer realistic?
3. As part of the proposed reform has there been consideration of whether the APVMA are undertaking unnecessary assessment work or whether the APVMA is assessing and requiring registration of products that is just not necessary, for example does the APVMA actually need to be assessing pool and spa chemical products?
4. In light of the proposed significant increase in costs of the registration system under the Government's proposal as it stands, how will the potential impacts on crucial existing products used by Australia's farmers be mitigated?
5. What consideration has been given to the potential negative impact on the introduction of new products?
6. Has the Department of Finance been involved in this process, particularly the proposed cost recovery model and associated industry fees and levies?
7. If so have they provided any advice about whether this model is in line with other government agencies cost recovery systems or relevant policies on cost recovery models?
8. Has DAFF or the APVMA used any consultants as part of this process in terms of assessing costs or efficiencies or other related work.
9. If so what work has been done and by which consultants or firms, what was the cost of that work and have the reports of those consultants been made public?

Answer:

1. To the extent possible, the anticipated real dollar costs and benefits were assessed in the Regulatory Impact Statement (RIS) for the *Better Regulation of Agricultural and Veterinary Chemicals* that was approved by the Office of Best Practice Regulation and which was released on 11 November 2011. A copy is available at www.daff.gov.au/__data/assets/pdf_file/0008/2046167/agvet-ris-16nov11.pdf.

Question: 185 (continued)

2. The Bill is currently scheduled to be introduced in the autumn 2012 sittings of Parliament with the first measures commencing from 1 July 2012 or upon Royal assent. This timeframe may need to be revised should consideration of stakeholder submissions identify that substantive changes are required to ensure that the Bill can achieve the desired outcomes of the Government's reform agenda for *Better Regulation of Agricultural and Veterinary Chemicals*.

3. Yes, the proposed *Better Regulation of Agricultural and Veterinary Chemicals* reforms include measures to determine the scale of an assessment appropriate to the nature of the application proposal, and therefore match regulatory effort to risk. Swimming pool and spa chemicals are currently subject to a streamlined application and assessment process under the Australian Pesticides and Veterinary Medicines Authority's (APVMA) low regulatory system for listable chemical products. APVMA regulation of pool and spa chemicals ensures that safe products are available to manage very serious disease organisms that can be transmitted via pools and spas. The most appropriate regulatory arrangements for this class of chemicals is being considered via a Council of Australian Governments' early harvest reform process.

4. It is not anticipated that the better regulation reforms will substantially increase the cost of the regulatory system. The continuation scheme is designed to promote public confidence in agricultural and veterinary chemicals while minimising impacts on industry.

5. The *Better Regulation of Agricultural and Veterinary Chemicals* reforms include several measures to promote the registration of new chemicals.

6. The Department of Finance and Deregulation (DoFD) has been involved in the development of the *Better Regulation of Agricultural and Veterinary Chemicals* reforms including a formal role in approving the associated RIS and supporting the development of the APVMA's interim cost recovery arrangements for the period 1 July 2012 until 30 June 2015.

7. See 6 above.

8. Yes.

9. Protiviti Pty Ltd was engaged to undertake a review of the efficiency and effectiveness of the APVMA. The cost of this review was $49 934. The report has not been made public. Protiviti Pty Ltd was also engaged to develop elements of the RIS for the better regulation reforms. The report has not yet been made public, though elements of the work appear in the RIS which has been publicly released. The cost of this work was $29 700.

Question: 185 (continued)

PricewaterhouseCoopers was engaged to undertake an activity based costing study to inform the APVMA's current cost recovery review. The cost of the study was $43 000. The outcomes of the study were reported in the cost recovery discussion paper.

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Question: 186

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

Senator COLBECK asked:

1. What assessments or analysis has the APVMA done to compare itself and its efficiency against similar regulators overseas, for example comparing the total number of applications that APVMA assesses and processes each year relative to its total annual budget compared to the similar regulator in the US and their total budget against applications processed?
2. Is it correct that APVMA uses Dept of Environment and Dept of Health to provide relevant analysis of products as part of the registration assessment process? Is that done via a service level agreement mechanism?
3. Are the service agreements between APVMA and DSEWPAC/DOHA available publicly? If not, why not? These and other documents are now being considered for voluntary publication.

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has conducted informal benchmarking of regulatory scope, function and costing against a number of overseas regulators, including the United States.

2. Yes.

3. No. These documents were in existence before the APVMA launched its Information Publication Scheme in May 2011. These documents did not meet the requirements of operational information for mandatory publication. The APVMA has received a request to access these documents and is currently considering the request through its Freedom of Information process.

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Agriculture, Fisheries and Forestry

Question: 187

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

Senator COLBECK asked:

1. The reforms include a proposal for a continuation application scheme, exactly what is that seeking to achieve and what will be the outcome of the continuation application scheme?
2. Under the continuation scheme, chemicals will be continued for between 7 and 15 years. What is the difference?
3. How will products be prioritised for continuation under the proposed scheme?

Answer:

1. The proposed continuation scheme for agricultural and veterinary chemicals is intended to ensure the ongoing safety of those chemicals. To ensure the entire agricultural and veterinary chemical inventory is systematically considered, the scheme will apply expiry dates for the market authorisation of chemicals and allow approval holders and registrants to apply on a regular basis for the continuation of active constituent and product registrations. The scheme will assure the integrity of the chemical products supplied in Australia in terms of the details of what was authorised and investigate whether any grounds exist to suspect that their authorised use may pose unacceptable risk to human or environmental health. The scheme would be separate from, but complement the existing chemical review arrangements system and facilitate the enhanced confidence of users, the community and our trading partners that agricultural and veterinary chemicals used in Australia meet their expectations for safety.

2. Following assessment, the Australian Pesticides and Veterinary Medicines Authority (APVMA) could continue approval or registration for a period of between seven and fifteen years based on factors that relate to the hazard of the chemical and the risks associated with its use.

3. The current proposed approach for the initial prioritisation of active constituent approvals has been set out in documents published to the APVMA website at www.apvma.gov.au/about/work/better_regulation/index.php.

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Question: 188

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

Senator COLBECK asked:

1. Schedule 1 talks about making decisions by using risk based frameworks. Are these risk frameworks available?
2. When will the accompanying risk frameworks for the proposed new registration system be released? Will there be opportunities for consultation on those frameworks?
3. Schedule 1 of the exposure bill proposes making trade and efficacy requirements for applications optional in some circumstances, what is the specific basis that will be used for determining whether this data will, and will not, be required?

Answer:

1. Yes.

2. The Australian Pesticides and Veterinary Medicines Authority (APVMA) intends to publish additional elements of the risk compendium before the Better Regulation of Agricultural and Veterinary Chemicals reforms are implemented. The APVMA expects to publish the Compliance and Enforcement Framework in mid March 2012; the Registration Framework in mid May 2012, and the Reconsideration Framework in mid June 2012. The operational detail in the Manuel of Requirements and Guidelines will be transposed into the risk compendium over the next two years. As this happens, the content will be reviewed and where necessary expanded upon in light of comments from stakeholders. The risk compendium is intended to be a living document that will be refined over time in response to operational demands and stakeholder views.

3. The circumstances where the APVMA will consider trade and/or efficacy will be specified in the Registration Framework, a draft of which is scheduled for public release in May 2012.