Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 103

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Comparison of cost of registering chemicals in Australia and elsewhere
Proof Hansard page: 77 (22/05/2012)

Senator BACK asked:

Senator BACK: One of the particular concerns I had, Mr Koval—perhaps you can correct the figures if I am wrong—is the actual costs associated with establishing pharmaceutical and biological products in Australia compared to other countries; I am only speaking now of food animal products. The quote that has been given to me is that, for pharmaceuticals for the farm animal product sector, our costs of establishing these pharmaceuticals in Australia is 66 per cent higher than Europe and 23 per cent higher than the USA; and for vaccines, biologicals, it is almost four times higher than Europe and seven times higher than the USA. Do those figures compute and confirm the information you have?
Mr Koval: No. I have heard stories or rumours or comment that an international study has been done that is yet to be released which is looking at the cost comparison of registering a veterinary product in Australia compared with like international regulators. I have not seen a copy of that report as yet. As I understand it, when the report came out three or four years ago, we compared very favourably. But the reform package is designed to try to lower the cost where we can by increasing efficiencies. So, as we go forward, we think the cost to industry will drop. I am happy to take that one on notice and see whether we can do some comparison with international regulators, if that is of use.

Answer:

We are not aware of the details of the costs of registering veterinary medicines in Australia versus other countries.

However, in 2007, the Animal Health Alliance (Australia) Ltd, in conjunction with the International Federation of Animal Health (IFAH), commissioned an international survey to benchmark the regulatory environment facing animal health companies. The survey found that the APVMA was a quality regulator making science based decisions to a world class standard in an open and transparent manner. The survey also found that industry saw the regulatory framework in Australia as much less of an obstacle to innovation in the animal health industry than in other countries. Overall, the survey ranked the APVMA as marginally behind the USA and well ahead of other Organisation for Economic Co-operation and Development country regulators.

The Department of Agriculture, Fisheries and Forestry understands that the results of a new IFAH Benchmarking Survey, carried out in 2011, will be released soon.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 122

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Requirements for spray applications by state
Proof Hansard page: 118 (22/05/2012)

Senator NASH asked:

Senator NASH asked: In terms of spray application requirements?
Senator Ludwig: Well more than that even, across all of the-many of the issues around agvet chemicals they are a different many.
Senator NASH asked: Could you take on notice and state by state provide for us the different requirements in terms of spray application?
Senator Ludwig: If it is possible, there are many that fit. There are multiple.
Senator NASH asked: In so far as it is possible, I am just generally interested in the differences across the states.
Senator Ludwig: We will have a look at it, it is significant. That is the problem is it is.

Answer:

Each state and territory has its own requirements for spray application, which are written in state legislation for control of use of agvet chemical products. A table summarizing state controls is provided at **Attachment 1**.
The controls are generally in relation to user training, powers to restrict application equipment or methods for applying pesticides, licensing of commercial operators, record-keeping requirements, neighbour notification, offences for causing off-target harm or injury, offences for advising another party to use a product in such a way that residues exceed mandated levels.
Each state department responsible for handling spray application inquiries provides information on its website. For example, a brochure published by the NSW Environment Protection Agency is available at:
www.environment.nsw.gov.au/resources/pesticides/10978Pesticidefactsheet.pdf

Similarly, the Victorian Department of Primary Industries has factsheets at:
www.dpi.vic.gov.au/agriculture/farming-management/chemical-use/agricultural-chemical-use/spraying-spray-drift-and-off-target-damage

The Queensland Department of Fisheries and Forestry also has factsheets at:
www.daff.qld.gov.au/4790_4906.htm

Biosecurity South Australia has information on its website:
www.pir.sa.gov.au/biosecuritysa/ruralchem/using_chemicals_safely

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 122 (continued)

ATTACHMENT 1: NATIONAL USE CONTROLS IN FORCE FOR AG & VET CHEMICALS IN AUSTRALIA as at March 2012

AGRICULTURAL CHEMICAL CONTROLS

Ag Chemical Control	QLD	NSW (EPA)	ACT	VIC	TAS	SA	WA	NT
Use of unregistered chemicals prohibited	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
General off-label use prohibited	Yes	Yes	Yes	No Prohibited for Vic restricted use chems e.g. S7 chemicals plus restrictions on rate, frequency, and all label prohibitions.	Yes	Yes Except for specifically exempted horticultural crops grown under approved QA schemes.*	Yes	Yes
Label prohibitions mandatory (offence to use contrary to a "DO NOT…" statement whether a Restraint or not (any differences shown)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Lower rate / frequency of use permitted	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Use for different pest in label crop/situation permitted	Yes	No	No	Yes	Yes	Yes	Yes	Yes
Agency can apply use controls on Restricted Chemical Products (RCP)	Yes	Yes	No	Yes Except for Vic restricted use chems	Yes	Yes	Yes By Health Dept and only if in Appendix J.	Yes

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 122 (continued)

Ag Chemical Control	QLD	NSW (EPA)	ACT	VIC	TAS	SA	WA	NT
Power to further restrict use (implement RCP controls)	Yes	Yes	No	Yes	Yes	Yes	S7 - as above	Yes
Power to restrict application equipment (method used to apply pesticide)	Yes	Yes	No	Yes	Yes	Yes	As per label	Yes
General user (farmer/commercial) training required	RCP only	Yes	Commercial only	Restricted Use Chemicals - includes RCPs	No	S7 & RCP only	Proposed	Commercial, S7 & RCP only
Licensing of commercial operators	Yes	Aerial only (Licensed Pest Control Operators (PCOs) by Workcover)	Yes	Yes	Yes	Yes Dept. Health	Yes	Yes Except PCOs by Health Dept
Commercial insurance required for licensed (aerial) operators	No	Aerial only	No	No	Aerial only	No	Aerial only	No
Treatment records required	Commercial/ contractors plus where required by Reg's	Yes	No	Yes	Commercial / occupational only	Only for commercial operators (Dept Health). Legal power available for other users.	Commercial (aerial and ground and certain restricted e.g. 1080, strychnine)	Yes Except home and garden
Neighbour notification (by owner/applicator) required (actual or optional)	No (unless label requires)	Yes Limited to public authorities or common residential area	Yes (S7 only)	Yes Limited to schools, hospitals and aged care services	Power for specific	Power available	Proposed if on label or RCP	No Unless label or specific issues e.g. S7
Neighbour notification required	Yes	Only if	Only if label	1080 only	1080 only	Only if	1080 and	1080 only

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 122 (continued)

Ag Chemical Control	QLD	NSW (EPA)	ACT	VIC	TAS	SA	WA	NT
(actual or optional) for vertebrate pest poisons	(Other legislation)	specified in a Control Order	requires			required by label. Power available.	strychnine only	
Employer / employee (eg owner, contractor, employee) liable for *misuse* offences	Yes (to limited extent)	Yes Includes other person causing or permitting harm	No	Yes	Yes	Yes (limited)	Yes	Yes Issue dependent
Offence for causing off-target injury or harm	Yes If licensed user or within a hazardous area	Yes	Only if label specifies	Yes	Yes	Yes Compliance Orders. Also under Public Health, EPA & OH&S laws	Proposed (current for phenoxys and Health laws)	Yes Crops and animals. Other offence different law applies
Offence for advising to use such that residues exceed mandated levels	Yes	No	No	Yes	Yes	No	No	Yes
Offence for advising another party in a manner so that the legislation (other than residues) is breached	Yes	Yes	No	Yes	Yes	No	No	Yes
APVMA deemed permits and related instructions have effect	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
APVMA suspension notices and related instructions have effect	Yes	Yes	Yes	Yes may require Order to effect	Yes	Yes. Gazettal required for immediate suspension	Yes	Yes
APVMA label grazing / fodder controls ("WHPs") have effect for chemical users	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 122 (continued)

Ag Chemical Control	QLD	NSW (EPA)	ACT	VIC	TAS	SA	WA	NT
Users required to keep use records? (The Livestock Production Assurance program requires records)	No (Some for QA and OHS)	Yes	No	Yes	Yes	No Except where label/permit requires. Can require records	Proposed	Yes (Two years)
Persons allowed to recommend off-label use?	Standards officers or officers of the crown	No	No	Yes May be liable for residues or adverse outcomes	No Except as allowed by legislation e.g. lower rate or frequency, pest not on label	No (As per Agvet Code)	No Except as allowed by legislation e.g. lower rate or WA not on label	No Except as allowed by legislation e.g. lower rate, NT not on label

In NSW, animal external parasiticides applied externally are currently defined as agricultural chemical products (pesticides) but being reviewed.
In VIC, "RUCP" includes S7 Agchem products, particular specified chemicals, eg atrazine, metham sodium and esters of 2,4-D, 2,4-DB, MCPA and triclopyr.
In WA, many of the controls are exerted by the Health Department, not WA Ag.
In SA *Regulations to restrict the general nature of these exemptions are scheduled for 2008. The exemption provisions are still in place.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 123

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Date of refusal of dimethoate application
Proof Hansard page: 121

Senator COLBECK asked:

Dr Bennet-Jenkins: Certainly. The APVMA have received an application for a permit, though the details of that application are not published but we are able to share some of the information about that permit for you. That was, as you have stated, an application to allow the use of dimethoate on tomatoes that were to be exported to New Zealand. We have refused that application because of the concerns about public health and residues. The very reasons why we no longer permit that use on tomatoes in Australia. The applicant has now sought a reconsideration of our decision to refuse that application and that process is still ongoing.
Senator COLBECK: When was the refusal?
Dr Bennet-Jenkins: I think it was probably towards the end of last year, but I would have to take on notice the exact timing. I don't have that with me.

Answer:

The permit application was refused on 23 December 2011.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 214

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Chemical Regulation Reform
Proof Hansard page: Written

Senator COLBECK asked:

1. Agforce raised concerns in their draft legislation submission that off patent products will be lost to industry just because of the mandatory review process.

2. How will the Department of Agriculture, Fisheries and Forestry ensure that chemical options are not lost to the industry because of the automatic review process?

Answer:

The scheme is designed to minimise impacts on affected industry while being effective at ensuring the ongoing safety of agricultural and veterinary chemicals.

The scheme applies an expiry date to existing approvals and registrations calibrated to the risks involved in using the chemical and invites applications to extend the approval or registration. The application process is low cost (less than $100 pa) and unlike schemes overseas does not require the generation of costly data to support the application. The Australian Pesticides and Veterinary Medicines Authority (APVMA) decides whether to grant the application. A decision not to grant the application will be based on whether there are reasonable grounds, founded in evidence, to believe that the chemical would pose an unacceptable risk to human or environmental health.

The scheme complements the existing chemical review scheme by sorting out those chemicals that need to be fully reviewed. The only way a chemical can be lost to the market is if the registrant chooses not to make a re-registration application or if the APVMA finds, following the re-registration application and chemical review process, that the chemical is not suitable for registration and use.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 215

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Chemical Regulation Reform
Proof Hansard page: Written

Senator COLBECK asked:

1. Do you agree with the Animal Health Alliance in their submission on the draft legislation that the Regulation Impact Statement has clearly identified the differences in regulatory processes and activities needed by the APVMA to manage risk for agricultural chemicals compared to veterinary chemicals?

2. Please explain your answer.

3. Are agricultural chemicals and veterinary chemicals currently managed differently in the registration process?

4. Can agricultural chemicals and veterinary chemicals be dealt with under the one regulatory structure proposed in the new legislation without any disadvantage in cost or regulatory burden to either group of chemicals?

Answer:

1. The Department of Agriculture, Fisheries and Forestry agrees that the regulation impact statement clearly shows that there are some differences in regulatory processes and activities. For example, the Australian Pesticides and Veterinary Medicines Authority has separate programs for agricultural chemicals and veterinary medicines. However, while the Regulation Impact Statement does not explicitly say that the same legislative tests apply to agricultural chemicals and veterinary medicines, it shows that the same legislative requirements apply.

2. Please refer to the answer to Question 1.

3. Yes.

4. Yes, there will continue to be sufficient flexibility for the Australian Pesticides and Veterinary Medicines Authority to equitably accommodate the differing requirements of various classes of chemicals.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 216

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Chemical Regulation Reform
Proof Hansard page: Written

Senator COLBECK asked:

AUSVEG in it submission on the draft legislation said,

"Australian vegetable growers rely on a range of targeted crop protection products to effectively combat pests and disease. As a representative body for Australian vegetable growers, AUSVEG holds great concerns that the proposed reforms will act as an economic disincentive for companies to register or re-register vital crop protection products in Australia. Our concern is that Australia's many vegetable growers will have access to a diminished range of crop protection tools and bear the brunt of registration and bureaucratic costs imposed by the APVMA, which will be passed on by companies to the grower.
The current proposed reforms of a continuous, periodic review process will only serve to increase the ongoing costs for registration, even where there are no concerns of risk."

1. Will an increase in the costs of registration by about 30% further reduce the availability of crop protection tools?

2. Have you advised the minister of this issue and what was the advice?

Answer:

1. The Department of Agriculture, Fisheries and Forestry does not accept that registration costs will increase by 30 per cent as a result of the better regulation reforms.

2. Not applicable.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 217

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Better Regulation Reform
Proof Hansard page: Written

Senator COLBECK asked:

1. Do you agree with Syngenta's submission to the Draft legislation that all risk manuals under the new risk-based framework must be owned and controlled by the APVMA to prevent external agencies from introducing new requirements without notification ("regulatory creep") or adequate consultation?

2. Please explain the reasons for your answer.

3. Explain your reasons for agreeing or disagreeing with Syngenta on the ownership and control of the risk manuals and risk based framework?

Answer:

1. Yes.

2. The Department of Agriculture, Fisheries and Forestry considers that the Australian Pesticides and Veterinary Medicines Authority (APVMA) should, in making its decisions, have to have regard to the risk framework that it establishes. While the Office of Chemical Safety in the Department of Health and Ageing and the Department of Sustainability, Environment, Water, Population and Communities will be closely involved in the development and on-going maintenance of elements of the risk framework; the APVMA will retain overall responsibility.

3. Please refer to the answer to Question 2.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 218

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Better Regulation Reform
Proof Hansard page: Written

Senator COLBECK asked:

1. Has there been a cost benefit analysis of the sun setting registrations or mandatory review process?

2. What research was done to support this approach?

3. What is the timeline for finalising the legislation?

Answer:

1. Yes

2. The Department of Agriculture, Fisheries and Forestry (DAFF) researched the basis of the approvals that underpin the current inventory of products registered by the Australian Pesticides and Veterinary Medicines Authority. DAFF also researched the approach that regulators in comparable countries take to managing their agricultural chemical and veterinary medicine inventories.

3. The legislation is scheduled for introduction later in 2012.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 240

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Performance Targets
Proof Hansard page: Written

Senator COLBECK asked:

1. Do you have any statistics or data to support the claim that "The most common reason applications are not finalised within statutory timeframes is because the applicant has been required to correct the application several times" (QON 184 February 2012).
2. Apart from applicants not providing the required information, what are the other main reasons that applications are not finalised within statutory timeframes?
3. Is the involvement of DAFF, SEWPaC, and DoHA with the APVMA processes another reason for delays?
4. Registrants have advised they are often unsure of the precise requirements necessary to achieve registration and that additional, unplanned requirements maybe required by other agencies such as DSEWPaC. What guidelines or technical support is offered to registrants to clarify information required by APVMA and DSEWPaC?
5. How is DAFF working with the APVMA to “improve the administrative efficiencies in the way in which the APVMA seeks and receives advice from SEWPaC and DoHA?
6. What outcomes have been achieved?

Answer:

1. From 1 July 2005 to present, the Australian Pesticides and Veterinary Medicines Authority (APVMA) has accepted and undertaken a full evaluation of approximately 7700 applications across all categories for both agricultural and veterinary chemical products. Of these, sixty-five percent have required the issue of two or more notices to address deficiencies in the applications before the APVMA could finalise the application.

2. Other main reasons for applications not being finalised within statutory timeframes include:
   - applicants either varying their application or providing new data during the evaluation process such that new or different issues need to be assessed;
   - there has been a significant increase in both administrative complexity, e.g. implementation of the data protection scheme in 2005, and technical complexity, e.g. introduction of the Joint Expert Committee for Food Additives and Veterinary Drug Residues in Food methodology in 2006 for veterinary product applications;
   - unexpected increases in workloads. For example, during 2010–11 there was a 22 per cent increase in the number of applications lodged with the APVMA. However, the recruitment, training and development of an evaluator takes up to 18 months.

Question: 240 (continued)

3. The APVMA has service level agreements with the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC) and the Department of Health and Ageing (DoHA) to provide technical advice within agreed timeframes. These timeframes ensure adequate time for the APVMA to review the advice, incorporate this into its overall evaluation, seek public comment when required, and prepare the final report for delegate determination. At times there have been delays in the provision of this advice.

   For some applications (e.g. imported vaccines), the APVMA may rely upon the DAFF Biosecurity import risk analysis to assist it determine whether the product may be harmful to animals, plants or the environment, which can delay APVMA processing.

4. The APVMA's *Manual of Requirements and Guidelines* sets out the requirements and guidelines for registering veterinary and agricultural products in Australia. The Manual is available at www.apvma.gov.au/registration/morag/index.php.

   The SEWPaC Environmental Manual is available at the Environment and Heritage Council website at www.ephc.gov.au/sites/default/files/CMgt_NChEM__ERAGM_for_Agricultural_and_Veterinary_Chemicals_200902.pdf

   The APVMA and agencies are available for pre-submission meetings or to respond to enquiries regarding proposed new products and uses and to advise on specific applications and data requirements. Applicants also have the opportunity to make an application to the APVMA to advise on the suitability or otherwise of proposed trial protocols and methodologies.

   Under the better regulation reforms, the APVMA is developing a risk framework, which is a compendium of documents, that will provide applicants with the detailed requirements for registering agricultural chemicals and veterinary medicines. Framework documents are being made available progressively at www.apvma.gov.au/about/work/better_regulation/risk_compendium/volume2.php. These reforms will also introduce a formal opportunity for pre-application assistance so that applicants can determine the precise requirements necessary in their specific case.

5. In order to improve the administrative efficiency of the interactions between the APVMA and other agencies including SEWPaC and DoHA, the department led a series of meetings between the APVMA, SEWPaC and DoHA to map and better understand the interactions. The Australian Government has also committed $800 000 over three years to establish an Independent Science Panel to assess and report publicly each year on the efficiency and effectiveness of the APVMA including the performance of the interactions between the APVMA and other agencies including SEWPaC and DoHA.

6. The mapping of the interactions between the APVMA and other agencies has identified a range of areas where improvements in administrative efficiency are possible.

Question: 240 (continued)

The APVMA is working with the other agencies to develop new Service Level Agreements to formalise new arrangements.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 241

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Service Agreements, QON 186 February 2012
Proof Hansard page: Written

Senator COLBECK asked:

1. Has the APVMA reached a decision regarding the public release of service agreements with the DSEWPAC and the DOH?

2. If not, when is a decision likely?

3. When was the FOI request made for these documents to be released?

Answer:

1. Yes.

2. Not applicable.

3. The request for information was made on 23 February 2012.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 242

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Risk Frameworks, QON 188 February 2012
Proof Hansard page: Written

Senator COLBECK asked:

1. Is the Compliance and Enforcement Framework complete?

2. Is the Registration Framework complete?

3. If so, please provide copies of these and any other completed risk frameworks.

4. Is the Reconsideration Framework on track to be released by mid July 2012?

Answer:

1. This framework is substantially complete and a draft has been published. However, its finalisation, and that of the other documents that make up the risk compendium, is subject to passage of the legislation.

2. As a result of extensive stakeholder consultation, the draft legislation that impacts on this framework is being modified.

3. Framework documents are being made available progressively at www.apvma.gov.au/about/work/better_regulation/risk_compendium/volume1.php.

4. Please refer to the answer to Question 2.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 243

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: New bill
Proof Hansard page: Written

Senator COLBECK asked:

1. What role did you play in the consultations to the new bill?

2. What role have you played in the development of the bill?

3. Did you give any advice on the development of the bill and specifically whether the mandatory review of chemicals would add to the regulatory burden of the organisation?

4. Did you advise the Minister against or raise concerns with any parts of the new legislation?

5. If so on what issues?

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) supported the Department of Agriculture, Fisheries and Forestry (DAFF) during the public consultation on the draft Agricultural and Veterinary Chemicals Amendment Bill 2011 (draft Bill) between November 2011 and February 2012. APVMA staff attended meetings with stakeholders and responded to questions about how the proposed reforms would affect the APVMA's day to day operations.

2. The APVMA provided detailed input to DAFF on the development of all aspects of the draft Bill. This included regular meetings as well as workshops on the drafting instructions and drafts of the Bill. The APVMA supported DAFF in its discussions with the Office of Parliamentary Counsel.

3. The APVMA does not provide policy advice on these issues. DAFF, as the responsible department consulted with the APVMA on how aspects of the draft bill might be operationalised.

4. Please refer to the answer to Question 3.

5. Not applicable.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 252

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Use of Gloricide in Australia
Proof Hansard page: Written

Senator SIEWERT asked:

Gloricide is a mix of 2,4-D formulas and metsulfuron methyl formulas plus other additives that are legal as individual chemicals but have not been approved for use in this combination.

1. Is the APMVA aware that this combination of chemicals is being used as a weed killer in Australia?

2. Has the APVMA had any correspondence about this chemical combination? Has the APVMA made any determination about whether this combination is legal to use?

3. If yes, what are the details of that determination? Have any conditions been placed on the use of this combination of chemicals? Will the APVMA be undertaking any further investigation into this combination of chemicals?

4. If no, will the APVMA be investigating the use of Gloricide in Australia and making a determination? Can you give a timeline as to when a determination will be finalised?

Answer:

1. Yes. The mixture is used under a current permit (Permit 11463) to control weeds according to the label instructions for use and the conditions of the permit. The permit document is available at permits.apvma.gov.au/PER11463.PDF.

2. Yes.

3. The individual products are registered for weed control in a range of situations as described on product labels. The permit contains the conditions under which the products may be used, including any restrictions or restraints on use, such as in aquatic situations.

   The Australian Pesticides and Veterinary Medicines Authority (APVMA) has no plans to undertake any further investigation into this combination of chemicals.

4. The APVMA has no plans to undertake any further investigation into the use of Gloricide in Australia.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 266

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Antimicrobial resistance
Proof Hansard page: Written

Senator DI NATALE asked:

Data about antibiotics is collected by the Australian Pesticides and Veterinary Medicines Authority from industry.

1. Is this data provided to the Authority on a voluntary basis only?

2. Is all data regarded as commercial in confidence? If not, what are the criteria for deciding which data is commercial in confidence?

3. Does this commercial in confidence limitation apply to applications for use of antibiotics as well? If yes, would it be correct to say that there is therefore no opportunity for medical doctors to comment on such applications? Is the Authority or the Department aware of whether this is the case in other countries?

Answer:

1. A range of different data requirements exist. Some, such as for an application, are required by law while others are voluntary.

2. Not all data is commercial in confidence. The Agricultural and Veterinary Chemicals Code Act 1994 includes a definition of confidential commercial information that reads as follows:

   Confidential commercial information, in relation to an active constituent for a proposed or existing chemical product, or in relation to a chemical product or a constituent of a chemical product, means:

   (a) a trade secret relating to the constituent or product; or
   (b) any other information relating to the constituent or product that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
   (c) information (other than trade secrets to which paragraph (a) applies or information to which paragraph (b) applies) that:
      (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and

Question: 266 (continued)

(ii) relates to the manufacture, distribution or supply of the constituent or product; and

(iii) if it were disclosed, could unreasonably affect the person, organisation or undertaking in an adverse manner;

but does not include:

(d) the making of an application for a permit for the use of an active constituent for a proposed or existing chemical product or for the use of a chemical product, if the use of the product proposed in the application is:

(i) a minor use; or

(ii) an emergency use; or

(e) any prescribed information relating to the making of an application for a permit, as mentioned in paragraph (d).

3. Yes

No

The Australian Pesticides and Veterinary Medicines Authority does not hold any information on whether or how regulators in other countries consult with medical doctors on applications.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 267

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Antimicrobial resistance
Proof Hansard page: Written

Senator DI NATALE asked:

What proportion of antibiotics given to animals are for therapeutic treatment, disease prophylaxis and growth promotion respectively? Please provide breakdowns by percentage.

Answer:

The Australian Pesticides and Veterinary Medicines Authority is currently compiling a detailed report on antibiotic usage covering the five financial years from 2005–06 to 2009–10. This will be published in the next few months and will contain the requested information.

The most recent report available is for the years 1999–2000 to 2001–2002 and is published at apvma.gov.au/publications/reports/docs/antimicrobials_1999-2002.pdf.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 268

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Antimicrobial resistance
Proof Hansard page: Written

Senator DI NATALE asked:

Is there a direct correlation between quantities of antibiotics given to animals and farming method? For example do animals which are kept in feed lots or other intensive farming systems require greater use of antibiotics? Please outline and provide any analysis performed by the Department on this area.

Answer:

The Department of Agriculture, Fisheries and Forestry has not conducted an analysis of antibiotic use for different farming systems.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 269

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Antimicrobial resistance
Proof Hansard page: Written

Senator DI NATALE asked:

Of all the antibiotics used in agriculture and for animals in Australia, including domestic pets, which if any are related to the classes of antibiotics currently deemed to be "critically important in human medicine" by the World Health Organisation?

Answer:

The table below lists antibiotics that are: used in human therapy that are also used in animals in Australia, including domestic pets, which are listed as "critically important in human medicine" by the World Health Organisation –

Antibiotic class	**Active constituent**	
Aminoglycosides	Gentamycin	
	Streptomycin	
	Framycetin sulphate	

Question: 269 (continued)

Cephalosporins (3rd & 4th generation)	Ceftiofur	A
	Cefovecin	A
Macrolides	Erythromycin	H&A
	Kitasamycin	A
	Oleandomycin	A
	Tilmicosin	A
	Tylosin tartrate	A
	Erythromycin	A
	Tulathromycin	A
	Spiramycin	A
Penicillins & Beta Lactamase	Amoxycillin	H&A
	Ampicillin	H&A
	Benzyl penicillin	H&A
	Clavulanic acid	A
	Cloxacillin	A
	Penethamate hydriodide	A
	Potassium clavulanate	A
	Procaine penicillin	A
Quinolones	Enrofloxacin	A
	Marbofloxacin	A
	Orbifloxacin	A
	Ibafloxacin	A
Streptogramins	Virginiamycin	A
Tetracyclines	Chlortetracycline	H&A
	Doxyxycline	H&A
	Oxytetracycline	H&A
	Tetracycline	H&A

All antibiotics used to treat animals are available on veterinary prescription only. To assist veterinarians to make proper decisions about the use of antibiotics, the Australian Veterinary Association has developed several guidelines on prudent and judicious use of antibiotics. These guidelines help to ensure that antibiotics are used effectively to control and treat animal disease while at the same time safeguarding public health.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 270

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR)
Proof Hansard page: Written

Senator DI NATALE asked:

According to the 2003 Joint Expert Technical Advisory Committee on Antibiotic Resistance Progress report by the Commonwealth Interdepartmental JETACAR Implementation Group (CIJIG) the Authority began a review of selected macrolide antibiotics December 2001 because of concerns over the potential risk to human health. The review was to provide the Authority with information to enable it to determine whether the existing uses of these macrolide antibiotics should continue in Australia. Please provide a full copy of this report.

Answer:

A full copy of the 2003 Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) Progress report by the Commonwealth Interdepartmental JETACAR Implementation Group (CIJIG) is available at www.health.gov.au/internet/main/publishing.nsf/content/EA33D21F7C12F3D8CA256F1900052727/$File/cijig_progress.pdf.

Rural and Regional Affairs and Transport Committee
ANSWERS TO QUESTIONS ON NOTICE
Budget Estimates May 2012
Agriculture, Fisheries and Forestry

Question: 271

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR)
Proof Hansard page: Written

Senator DI NATALE asked:

Recommendation 3 of the Report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance recommended that an appropriate government authority/ies control all importers of antibiotics (for any use other than for human patients) and that they must provide detail of distribution and information based on amounts of active ingredients, with a stronger audit trail from importer to end user and that results are made public. Has the recommendation been implemented and are the results available to the public, as recommended?

Answer:

The government response to the Joint Expert Technical Advisory Committee on Antibiotic Resistance report is accessible at www.health.gov.au/internet/main/publishing.nsf/content/F57A4B816B1AA634CA256F1900041160/$File/CWealth%20Govt%20Response%20to%20JETACAR.pdf. The government response to Recommendation 3 focused on the reporting and auditing of antibiotic use in humans and animals. The Australian Pesticides and Veterinary Medicines Authority (APVMA) collects voluntarily supplied information from registrants on the quantity of veterinary antimicrobial products sold in Australia. The APVMA has prepared a report based on antimicrobial sales data for the period 2005–06 to 2009–10 and expects that it will be published by the end of 2012.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 272

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR)
Proof Hansard page: Written

Senator DI NATALE asked:

Recommendation 4 of the Report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance recommended reviews of antibiotics which included risk analysis of microbial resistance safety. I understand this has occurred for new veterinary antibiotics but has this applied to existing antibiotics?

1. When data is collected regarding use of antibiotics, does the Authority always require that the use is specified (eg growth promotant or prophylaxis)?

2. If the use of an antibiotic originally registered as a growth promotant is changed to prophylactic use does this automatically trigger a thorough review of the efficacy of this antibiotic as a prophylactic?

Answer:

Risk analysis of microbial resistance safety is undertaken for new veterinary antibiotics and major extension of use for existing antibiotics.

1. Yes.

2. Such an application would be considered in the light of the Joint Expert Technical Advisory Committee on Antibiotic Resistance's (JETCAR) Recommendation 1, which states that in-feed antibiotics used in food-producing animals for growth promotant purposes, or other routine uses where duration and dose level are the same, or very similar, should not be used unless they:
   - are of demonstrable efficacy in livestock production under Australian farming conditions; and
   - are rarely or never used as systemic therapeutic agents in humans or animals, or are not considered critical therapy for human use; and
   - are not likely to impair the efficacy of any other prescribed therapeutic antibiotic or antibiotics for animal or human infections through the development of resistant strains of organisms.

   The boundary between 'prophylactic use' and 'therapeutic use' is not always clear and so such an application would receive careful scrutiny to ensure that it did not infringe on the policy set out in the above recommendation.

Question: 272 (continued)

An application of this type would be unlikely, because the veterinary chemical industry is well aware of the JETACAR report and recommendations and of their implications. Nevertheless, if an application was to be made to vary the use of a growth promotant to include a prophylactic/therapeutic use, the application would be assessed like any other application for a major extension of use.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 273

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance
Proof Hansard page: Written

Senator DI NATALE asked:

Recommendation 16 of the Report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance called for regularly updated "antibiotic use guidelines" both human and veterinary. The recommendation also called for evaluation of the effectiveness of these "guidelines" every 5 years. Have any updates or evaluations been carried out pursuant to this recommendation? If yes, please provide.

Answer:

The Australian Pesticides and Veterinary Medicines Authority's (APVMA) guideline on data requirements for antibiotic resistance is incorporated in the Veterinary Manual of Requirements and Guidelines (Vet MORAG) as *Part 10 - Special Data: Antibiotic Resistance*. This guideline has not been updated since it was published post-JETACAR in 1999. Australia has been an active participant in the development of OIE/FAO/WHO antimicrobial resistance guidelines for managing antimicrobial resistance. The APVMA will adopt these guidelines once they are finalised and published.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 274

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Antimicrobial resistance
Proof Hansard page: Written

Senator DI NATALE asked:

1. Is the Authority aware of whether polypeptides are fed to agricultural livestock in Australia?

2. If yes, are polypeptides used commonly?

3. Is the Authority aware that polypeptides are now being used as last resort antibiotics in human medicine because of growing resistance to other antibiotics?

4. What is the Authority's assessment of the risk of cross resistance?

Answer:

1. Yes.

2. The polypeptide zinc bacitracin is used widely for the treatment of necrotic enteritis caused by the bacteria Clostridium perfringens (types A and D) and as an aid in the prevention of necrotic enteritis in poultry. Zinc bacitracin is also incorporated in ointments in combination with other veterinary chemicals to treat infections of the eyes and ears of animals. All products that contain zinc bacitracin are used under veterinary prescription only.

3. Yes.

4. The Australian Pesticides and Veterinary Medicines Authority has not conducted any assessment on the risk of cross resistance of zinc bacitracin.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2012

Agriculture, Fisheries and Forestry

Question: 293

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Carbendazim
Proof Hansard page: Written

Senator XENOPHON asked:

In November last year, the APVMA announced it was going to reduce the MRL of carbendazim in the Food Standards Code to zero following a review of the fungicide's use. This 'ban' would have come into effect from the second quarter of 2012.

However, after a result of discussions with FSANZ, it was announced in February 2012 that there would be a 'review' of the ban.

a. Can you please indicate the process – for example, the representations and advice received by the APVMA – that led to a review of the decision to ban carbendazim in Brazilian orange juice concentrate imports?

b. Which groups/individuals provided this advice?

c. Did the APVMA agree with the advice, considering its initial decision to apply a zero MRL?

d. Can you indicate how this review is progressing?

Answer:

a. Following discussions with Food Standards Australia and New Zealand (FSANZ) the Australian Pesticides and Veterinary Medicines Authority (APVMA) agreed to delay amendment of the Food Standards Code (FSC) by 12 months to allow FSANZ to complete a risk assessment and to recommend new MRLs for imported produce, including Brazilian orange juice concentrate.

b. Names of interested parties that provided advice in respect of the separate FSANZ process should be sought from FSANZ.

c. The APVMA has no role in the separate FSANZ risk assessment for imported produce or in establishing a different limit for imported orange juice.

d. The APVMA review of carbendazim is continuing.