Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2013

Agriculture, Fisheries and Forestry

Question: 37

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Environmental Assessment Costs
Proof Hansard page: 66

Senator COLBECK asked:

Senator COLBECK: So, under the arrangement that you have with SEWPaC, a level 1 environmental assessment costs $12,605, a level 2 environmental assessment costs $3,255 and a level 3 environmental assessment costs $620?
Mr Matthew: I would like to check if those figures have moved on but essentially they were the figures that we spoke about in October last year. If the agency accepts the work order to do that work—in this case, environmental level 1—the expectation is the work will be done and we will provide them the value as stipulated in the table.
Senator COLBECK: But you need to confirm on notice?
Mr Matthew: I would like to take on notice if we have in fact revised any of those fees since July 2010. There were negotiations underway late last year to revise fees to take account of current costs. But I might add that, if there is a considerable amount of additional work and we cannot agree that it fits one of the predetermined levels, then work orders can be constructed that relate back to the hourly rate.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) aims to nominally recover 40 per cent of the agency assessment fees from application fees, with the balance coming from a levy based on product sales. This approach was agreed by the Signatories Working Group (SWG) when the then National Registration Authority (now the APVMA) was established in 1995.

A level 1 environmental assessment from the Department of Sustainability, Environment, Water, Population and Communities costs APVMA $41 290, of which the application fee covers 31 per cent ($12 605) of the cost. A level 2 environmental assessment costs APVMA $13 606, of which the application fee covers 24 per cent ($3255) of the cost. A level 3 environmental assessment costs APVMA $2302, of which the application fee covers 27 per cent ($620) of the cost.

The APVMA's recently published Cost Recovery Impact Statement for 2013–15 includes changes that will restore application fees to the 40 per cent recovery target.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2013

Agriculture, Fisheries and Forestry

Question: 38

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Operating Costs
Proof Hansard page: 67

Senator COLBECK asked:

Senator COLBECK: Okay, so can you give me an idea of what three months of operating costs sits at?
Mr de la Fosse: The three months operating financial reserve is $7 million.
Senator COLBECK: If you go back to page 198, could you confirm the numbers in the 2010 to current day column as to their currency. I suppose the other question around that is: is there some form of rise, fall or adjustment process that is part of that agreement? The DoHA one, for example, I think according to the information I have is the 2010-16 agreement—so it is over a period of time. It would be reasonable to expect that there might be some adjustment clauses within that particular section.
Mr Matthew: I will try and get that correction within the session now.

Answer:

The '2010 to Current Day' column was current.

The service level agreements between the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the agencies outline that each year the APVMA and the agency '*will review the Schedules and attachments and make any adjustments to those as agreed between them*'.

The agency service level agreements commenced in 2001-02 and there have been agreed adjustments made each year. In relation to fee structures, in most cases the adjustments have been upwards, however there has been one adjustment downwards.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2013

Agriculture, Fisheries and Forestry

Question: 39

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Number of Environmental Assessment Charges
Proof Hansard page: 67

Senator COLBECK asked:

Senator COLBECK: But if they come up against a big job that does not fit within the parameters of the agreement you have in place then there is capacity for them to say 'sorry we cannot do that for the fee in that particular category. We need to do it on an hourly basis' or some other form of agreed process?
Mr Matthew: Yes because if they do not accept to undertake the work order that we offer them, there can be a process of discussion to see if it would more neatly fit under professional services or some other mechanism.
Senator COLBECK: How often would that happen?
Mr Matthew: I am not sure of the number of times that has happened in recent times but it does happen from time to time. I might have to take that on notice.

Answer:

To date in 2012–13 there have been six instances and in 2011–12 there were two instances where the work in question did not fit the parameters of the service level agreement.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 40

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Research on Pesticide Spray Drift
Proof Hansard page: 68

Senator EDWARDS asked:

Senator EDWARDS: The decision to implement mandatory buffer zones on pesticide levels—has any work been done to assess whether that has been helpful in reducing spray-drift issues?
Mr Koval: There is a group on spray drift, and APVMA looked at a couple of chemicals in the products around. They are looking at the effectiveness of them. I am not aware of any research done on that, but I am willing to take it on notice and have a look—
Senator EDWARDS: Yes, if you would not mind. It is a bit of an issue.

Answer:

The states and territories have been monitoring the effectiveness of mandatory buffer zones on product labels since they were introduced in 2010.

New South Wales and Victoria reported a reduction in concerns raised about spray-drift management, due to larger buffer zones and improved education, neighbour notification and industry advice as well as better product stewardship information accompanying the mandatory instructions.

In addition, some manufacturers are heavily promoting the ‘SprayWise Decisions’ program, which provides useful information on planning for spraying and interpreting weather conditions. More information is available at www.spraywisedecisions.com.au.

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ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2013

Agriculture, Fisheries and Forestry

Question: 41

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

Senator DI NATALE asked:

Has the Authority completed the 'Quantity of Antimicrobial Products Sold for Veterinary Use in Australia" antibiotics report? What is the status of this Report and when is it due to be released publicly?

Answer:

The report on the quantity of antimicrobial products sold for veterinary use in Australia from 2005-2010 (five financial years), has been drafted and is undergoing quality control checking, including checking with companies that the data they provided was complete and accurate. It is expected that the report will be ready for publication in coming months.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2013

Agriculture, Fisheries and Forestry

Question: 42

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Banning of Fenthion; Change of label Directions and Reduced MRL
Proof Hansard page: Written

Senator BACK asked:

1. In recent years, the APVMA lifted the MRL on fenthion from 2mg/kg to 5mg/kg.

The MRL has now been set at the level at 0.2 mg/kg.

In response to questions as to why the acceptable level has been decreased so dramatically, APVMA advised that the 5mg/kg MRL referred to long term dietary exposure to fenthion.

Did the APVMA conduct reviews on both long term and short term exposures at the same time? If not, why not?

2. If APVMA only reviewed long term exposure and failed to consider short term exposure, has APVMA potentially put young children in harm's way?

3. If the APVMA ruled that 5mg/kg was a safe MRL, why did the APVMA see the need to make such drastic cuts in the new MRL of 0.2mg/kg?

Answer:

1. The change in the fenthion Maximum Residue Level (MRL) from 2 mg/kg to 5 mg/kg occurred over 15 years ago, in 1997. This was associated with an application from the manufacturer of the product. At that time, the then National Registration Authority (now the Australian Pesticides and Veterinary Medicines Authority or APVMA) and the National Food Authority (now Food Standards Australia New Zealand or FSANZ) did not undertake short-term dietary exposure estimates as the methodology did not exist, either in Australia or internationally. Therefore, the application to increase the MRL was granted on the basis of a long-term dietary exposure assessment only.

   Short-term exposure assessments commenced in Australia after 2000, after a policy decision taken jointly by the Therapeutic Goods Administration within the Australian Government Department of Health and Ageing (DoHA), FSANZ and the APVMA.

2. The 1997 application was granted on the basis of the best available science and international best practice exposure assessment at the time. In hindsight, a risk to young children existed but was not known.

3. The APVMA reduced the MRL on the basis of the acute reference dose (the short-term dietary exposure standard) for fenthion set by the Office of Chemical Safety in DoHA.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 43

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Registration of AgVet Chemicals
Proof Hansard page: Written

Senator BACK asked:

1. How exactly does the current APVMA registration process contribute to the risk-based national framework for managing the use of AgVet Chemicals promoted by the PSIC, particularly in terms of its cost-effectiveness and utilisation of government and corporate resources?

2. Approach to risk:
   a) To what extent are specific risks being identified, prioritised and appropriately managed in the registration process, OR is risk avoidance currently defaulting to a bastardised form of the precautionary principle which requires registration applicants to substantiate the absence of risk even when significant hazards or adverse outcomes are unlikely, or can be reasonably expected to be negligible?

3. Robustness of responding to registration applications:
   a) To what extent does the current review process and advice to, or requirements of, registrants (particularly of failed applications) inform and contribute to appropriate identification and management of risk, OR
   b) Is there a failure within the agency to properly identify and communicate the significant risks related to a particular product application, OR (as an extension of that)
   c) Despite the time taken for an application to be considered, why is there not some advice routinely supplied to an applicant which would enable them to address particular issues of risk, including for products which are approved.

4. To what extent does the inflexibility of (the application of) MORAG and other parts of the registration system inhibit the registration of innovative, low-risk products or changed label directions which would enhance animal health and welfare in Australia?

5. To what extent does the difficulty of registering veterinary chemicals in Australia, particularly those known to be effective and widely used elsewhere, contribute to risk by encouraging inappropriate and illegal off-label use of both registered and unregistered chemicals (such as Ag versions of the active) and/or the continued use of already registered but less effective or higher risk alternatives?

Question: 43 (continued)

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) registers agricultural chemical and veterinary medicine (agvet chemical) products and establishes label instructions. State and territory regulators refer to label instructions in enforcing proposer use. APVMA regularly consults with partner agencies, including health and environment, as part of the registration process to ensure ongoing cost-effectiveness and appropriate use of government and corporate resources.

2. The APVMA's risk assessment takes into account the known hazards and the likely points of exposure and determines the appropriate level of risk management that needs to be applied for safe use of the product. A key component of the government's agvet chemical reforms is the development of a comprehensive risk compendium (which will be published progressively by the APVMA) that explains how the APVMA applies the suite of agvet legislation, its policies and its decision-making processes. The primary risk management mechanism is via the approved label instructions, but the statutory arrangements provide for other controls, such as restricting use to specifically trained personnel where that is necessary and appropriate to manage specific identified risks.

   The flexibility of APVMA's risk assessment process to deal with less risky substances, as well as the changes from the Australian Government's proposed agvet chemical reforms to ensure the APVMA matches regulatory effort with risk, is addressed in Question 4.

   The APVMA does not require applicants to substantiate the absence of risk. There is an inherent level of risk with any use of a chemical. The scheme is built around the management of risk. Where risks cannot be managed and there is a likelihood of undue harm occurring, the APVMA's legislation requires that the APVMA must not grant the application for registration.

3.

a) Registrants are required to provide to the APVMA information on the hazards and likely exposures relating to the chemical product proposed for registration. The APVMA can then assess the chemical product's risks and consider their management.

   Where applications are refused because the APVMA is not satisfied, the applicant is provided with the reasons for the decision. This assists them to determine whether or not to proceed with the proposal and re-submit another application. The APVMA also makes itself available to provide advice as to what sorts of information it would need to undertake a risk assessment if that is necessary.

b) No. See response to part a) above.

c) During the assessment of an application, the APVMA advises the applicant as soon as possible if areas are identified where the APVMA is not satisfied of the relevant statutory criteria.

Question: 43 (continued)

4. The APVMA's Manual of Requirements and Guidelines (MORAG) provides applicants with a guide of the information required for a risk assessment. Applicants may provide other types of information to allow the APVMA to fully understand the hazards and risks of the proposal.

   The APVMA can also tailor assessments to only consider sufficient minimum factors to satisfy the APVMA that safety and efficacy statutory criteria are met. These are referred to as modular assessments and allow the assessment effort to be aligned with the risks associated with the proposal in the application. These arrangements apply to all applications for chemicals, including innovative low risk products. The APVMA can also assess applications for access permits for uses of chemicals in unique and emergency situations, as well as for research and innovation purposes.

   The government's proposed agvet chemical reforms will also ensure the APVMA matches regulatory effort with risk. Optional consideration may be given to certain matters. For example, subsections 5B(3) and 5C(3) provide for efficacy and trade criteria to be considered only to the extent relevant to the particular assessment being undertaken by APVMA. Different registration pathways may be provided for chemicals with different risk profiles, such as streamlining the process for registration for products of lower regulatory concern through amendments relating to listed chemical products. Regulatory effort (by the APVMA and its regulatory partners) and the burden imposed (on applicants and registrants) will be balanced with the risks to health and safety. The APVMA will be required to determine the scale of an assessment appropriate to the application or reconsideration before it.

5. Australian registration of veterinary chemicals used overseas is relatively straightforward where it is supported by sound scientific information. The APVMA permit process allows access to unregistered uses. While the APVMA administers its legislation so that it minimises the risk of encouraging inappropriate and illegal off-label use of registered and unregistered chemicals, the government recognises that the legislation does not operate as effectively as it can. This is why the government has introduced reforms to the APVMA's legislation, which will among other things address the perceived difficulty of registering veterinary chemicals in Australia.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2013

Agriculture, Fisheries and Forestry

Question: 44

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Support for Goat Industry
Proof Hansard page: Written

Senator BACK asked:

Although the goat industry pays levies to MLA, Animal Health Australia and the National Residue Survey, it is deemed too small for investment in animal health products. The industry exports 30,000 tonnes of goat meat annually, and exports 85,000 goats. The industry is crying out for investment, so what can the APVMA do to aid the industry, what guidance can it give, and can it work with the industry and Australian Veterinary Association to administer chemicals through minor use permits?

Answer:

Legislation allows the Australian Pesticides and Veterinary Medicines Authority (APVMA) to issue permits in three situations: minor use; emergency use; and for the purposes of research. Minor use means a use of a product that would not produce sufficient economic return to an applicant to meet the costs associated with registering the product. Emergency use relates to emergencies such as the incursion of exotic pests and diseases.

The current size of the goat industry means that for more common uses the APVMA can be prevented from issuing minor use permits because the use of the chemical would generate significant revenue, thus conflicting with the minor use definition.

The metabolism of the goat is substantially different to other comparable species, such as sheep and cattle, and therefore it is not possible to extrapolate from this use of products to a proposed use on goats. This necessitates the submission of goat-specific information in order to undertake the required risk assessments.

Where urgent circumstances arise that require animal treatment, for example to alleviate suffering, veterinarians may be able to use their prescribing rights which allows ‘off-label’ use of registered products.

The APVMA is open to discussing with the goat industry whether particular circumstances of use would be considered ‘minor use’ and to outline the information that would be necessary to inform its risk assessment.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 45

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

Senator DI NATALE asked:

1. Are any cephalosporins being used now in animals? Either food animals or companion animals? If so what are they? Has there been a change in categorising of drugs as 3rd or 4th generation at any time during the past 5 years? If so please provide details as to what these changes were and why the change was made.
2. What is the difference in terms of risk to human medicine between the various generations of cephalosporins?

Answer:

1. Yes, cephalosporins are registered for use in animals. These are

1st generation	Cephalexin	Dogs; cats
	Cephapirin	Dairy cattle (intrauterine – endometritis)
	Cephalonium	Dairy cattle (dry cow intramammary – mastitis)
2nd generation	Cefuroxime	Dairy cattle (intramammary – mastitis)
3rd generation	Ceftiofur	Cattle & horses (respiratory infections); dogs (urinary infections)
	Cefovecin	Dogs and cats (wounds and abscesses, and skin and urinary tract infections)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is not aware of a change in categorising drugs as 3rd or 4th generation in the past five years.

2. Generations of cephalosporins differ in their structure and antimicrobial properties. The exact categorisation can vary depending on which authority is used. As a general rule, each newer generation of cephalosporin is more effective against Gram-negative infections and less effective against Gram-positive infections, although 4th-generation cephalosporins tend to be broad-spectrum. Third- and 4th-generation cephalosporins are regarded as of critical importance in treating several serious human infections. The APVMA manages these risks by undertaking rigorous and comprehensive risk assessment on all new antimicrobials for use in animals, major extensions of use of existing antimicrobials and reviews of currently registered antimicrobials.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 46

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

Senator HEFFERNAN asked:

In response to the APVMA Answers to the October 2012 Senate Estimates Questions:

1. When does a mixture or concoction of chemicals become a Chemical Product that requires APVMA Approvals and Registrations?
2. If a Tank Mixture has been given a name and has its very own MSDS identifying the constituents of the product and defining it a risk assessment rating such as a Poison Schedule, such as Gloricide; when does that Formula become recognised as an Agricultural Chemical Product under Australian Law?
3. If as you claim that a range of herbicides on Permit 11463 can be mixed together as a new formula/product and used under that Permit, at what point do you draw the line? Is it acceptable to allow the rest of Australia to operate under the Permit System and create random super poisonous concoctions that can be used without restraint, due to the lack of conditions the APVMA has imposed on specific Product Labels/Permits and the culture of advice the APVMA provides Industry, Local Government, State Governments, Budget Senate Estimate Committee's etc
4. Is it true that if a private company wanted to develop a new product such as Gloricide and commercialise its use under a trade name and individualised MSDS, it could bypass APVMA Product Registration Fees, Permit System, Product Testing Requirements, WH&S, Environmental Duty of Care?
5. Would if be fair for a Private Company to develop a new Chemical Formula/Product that depends on operators mixing up S5 and S6 products and inform the workers in the MSDS that they are using a 'Non-Hazardous Product' and because it is diluted it is safe to use and does not warrant any protective equipment, even with estrogen mimicking substances such as 2,4-D and Gloricide?
6. Is the APVMA aware of the WH&S Rating of Gloricide established in the MSDS for the product and do you agree that workers are fully informed of the dangers to themselves, the Community and the Environment?
7. Does the APVMA think it appropriate that they have allowed Products such as 2,4-D and Metsulfuron methyl to be re-registered and Labels re-approved by the APVMA in return for money, if the product MSDS/Label does not contain one empirical direction as to where you can use the products?
8. The APVMA is more than aware of the risks of using Gloricide, 2,4-D and Metsulfuron methyl, as per the restrictions on Permit 10540. Why has the APVMA not provided one direction on Amicide or Metsulfuron Labels that regulates the risks the APVMA has established, surely a minimum setback distance is necessary or some empirical guidance or restrictions?

Question: 46 (continued)

9. The APVMA claim in Response to the October Questions, that the UNEP is not responsible for implementing the Rotterdam Convention due to Australia not being a signatory to the Enforcement component of the Convention, who is responsible for Australia's Compliance with the Rotterdam Convention and is this a priority?
10. Is it true that 2,4-D product can be used as precursor products for 2,4,5-T aka Agent Orange, under variable conditions and the mixing of perhaps hundreds of different chemicals never tested in combination with earth other?
11. Is it true that Gloricide, 2,4-D and Metsulfuron methyl are being used in and around Aquatic Areas, as defined by Schedule 3A, Part 3, Ag Vet Chemical Code Regs 1995 by the SCRC and private contractors for hire?
12. Is it true that Gloricide, 2,4-D and Metsulfuron methyl are being used in and around Critical Habitat for Endangered Acid Frogs etc by the SCRC?
13. How much area of land has been treated with Gloricide and how many times per year are Gloricide, 2,4-D and Metsulfuron methyl being applied to these sandy soils and wetlands?
14. Is it true that Gloricide, 2,4-D and Metsulfuron methyl are being used right up to the edge of the vegetation on the coastal foredune and up to and over the edge of Coastal Steams as per the Utube Videos on the 'dontpoisonmeplease' channel?
15. In this situation; Coastal Foreshores, Wetlands, Sandy Soils, Endangered Acid Frogs, high rainfall, perched water tables, what setbacks should the APVMA require for each of the Products to meet their respective Label Conditions?
16. The products Gloricide, 2,4-D and Metsulfuron methyl are claiming by SCRC, Queensland Government, OCO to be using within the Label and Permit Instructions. Does the APVMA CEO agree that the Gloricide Program is fully compliant with relevant Australian Laws including Chemical Regulation, WH&S, Environmental Protection etc?
17. Considering the presence of perhaps some of the most sensitive Endangered Species on our planet, Acid Frogs; did the APVMA consider this when you approved the Gloricide program to continue in May Budget Senate Estimates and in correspondence to a wide range of organisations and Regulators?
18. It is the case that the Office of the Commonwealth Ombudsman, Office of the Queensland Ombudsman, Queensland Crime and Misconduct Commission, etc have refused to undertake an investigation into the very serious allegations levelled at the APVMA regarding the use of Unregistered Agricultural Chemical Products and using Registered Agricultural Chemical Products against their Label and Permit Advice?
19. Is it true that the APVMA CEO has refused to provide a Statement of Reasons to Adam Presnell, Director of ATP Environmental pty ltd, regarding the CEO's decision to allow Gloricide to continue illegally, thus benefit corrupt contractors prepared to risk the lives of their staff on deliberate misinformation? If so can you justify why the APVMA is refusing to clarify and demonstrate the decision of the APVMA CEO to allow Gloricide to continue despite not using a Registered Chemical Product, despite all constituent product not registered for use in or around Aquatic Areas, despite the explicit Permit Conditions regarding use in and around Aquatic Areas, despite the application of multiple, selective hormonal herbicide concoctions to Endangered Acid Frogs etc?

Question: 46 (continued)

20. Is it true that Formal Complaints concerning the conduct of the CEO of the APVMA, regarding the provision of deliberately False and Misleading Information etc, were lodged with DAFF, Minister Ludwig and the PM? The Minister and the PM have failed to investigate and respond to the matter as have the OCO. Has the APVMA and the Gillard Government undertaken due legal process to concerns raised by Adam Presnell if no one is or has investigating the matter independently at a Local, State or Federal Level?
21. Being that the responsible Ministers have failed in their duties to investigate a CEO of a Chief Government Regulator and considering the $500 000 price tag of a prosecution against the APVMA by a small private company that has been sent broke because they refused to use these products illegally; is it appropriate the complaint be openly and transparently examined and for various decisions by the APVMA CEO to be explained both to the Parliament, the Queensland Government and to the Complainant?
22. Is it true the Federal Government is claiming it is a State Issue and the State Government is calling it a Federal Issue and Local Government Issue and that not one investigation by an independent authority has being undertaken?
23. If the APVMA is the regulator of Chemical in Australia, is it proper that the APVMA at least attempt to regulate the control and use of Chemicals in Australia by providing more honest information in the Labels and MSDS with some empirical data?
24. South Australian EDO Solicitor Ms Ballantyne claims: "There is currently a 100m buffer zone for all 2,4-D products, whereby a buffer zone of 100 metres must be maintained between field edges and downwind water bodies and native vegetation. Is this buffer zone applicable to South Australia or all of Australia?" Can you confirm or deny this claim, do you know who prepared this regulation/policy and when?
25. Did the APVMA mislead the Parliament in October when you claimed their are no standards on the Label thus none exist
26. If the APVMA was aware the Gloricide, 2,4-D and Metsulfuron methyl are being used contrary to the Permit Conditions, why has the APVMA condoned and defended this highly risky research without a valid Permit?
27. The Manufactures of Amicide and Brushoff claim that their Products are not registered or approved for use in or around aquatic areas with very serious disclosures including: Amicide: PROTECTION OF WILDLIFE, FISH, CRUSTACEA AND ENVIRONMENT: DO NOT contaminate streams, rivers or waterways with the chemical or used container. Brushoff: Toxic to aquatic organisms may cause long term effects in the aquatic environment. Does it claim anywhere on Permit 11463 that either 2,4-D or Metsulfuron methyl can be used in and/or around Permit Areas?
28. Is it true that the SCRC, BQ, WH&SQ, DERM, OQO, CMC etc are allowing the Gloricide Program to continue due to correspondence you have issued claiming that the APVMA is not investigating the matter or has investigated the matter and officially endorsed the Gloricide Program.
29. Is it true that SCRC claim or have claimed that the Gloricide Program is operating partly under a Research Permit and partly under a Minor Use Permit? If this is the case would this concern you that neither Permit adequately covers the legitimacy of the work.
30. Is it true that the Queensland Government has delegated regulating the use of chemicals and management of endangered species entirely to SCRC?

Question: 46 (continued)

31. Does the SCRC, as proud Designers, Suppliers and Users of Unregistered Chemical Products, have a Chemical Engineer or appropriately qualified WH&S Expert in its staff to manage the risks?
32. With regards to the APVMA previous response to questions at the October 2012 meeting, Queensland State Control of Use Legislation the Chemical Usage Act 1988, Section 11A states 'a person must not make a claim about the use of an unregistered chemical' unless 'the use of the unregistered chemical (such as Gloricide) is authorised by a Permit. For the life of me i can not find and thing on Permit 11463 that claims that the Permit can be interpreted as allowing use of mixes of registered products. Where in Permit 11463 does it allow random concoctions to be used?
33. How does the use of Gloricide under Permit 11463 differ from the risks of using a Gloricide type product under Permit 10540?

Answer:

1. A mixture of chemicals requires Australian Pesticides and Veterinary Medicines Authority (APVMA) approval or registration when it meets the following definition of an agricultural chemical product, as described in the Agricultural and Veterinary Chemicals Code Act 1994, section 4. This states that ‘an agricultural chemical product is a substance or mixture of substances that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:
    1. Destroying, stupefying repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or thing; or
    2. Destroying a plant; or
    3. Modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or
    4. Modifying the effect of another chemical product; or
    5. Attracting a pest for the purpose of destroying it.’

2. A mixture of chemicals is considered an agricultural chemical product when it meets the definition provided in part 1. above. A tank mix of registered chemical products is not itself another chemical product. The making of a tank mix is not an offence under state control of use legislation, unless product labels specifically prohibit mixing of one product with another.

3. Permit PER 11463 was issued to allow a range of registered products to be used to control environmental weeds in a range of situations, such as bushland, forests, wetlands, coastal areas and non-agricultural areas for which there are no registered alternatives. This permit allows use of products in situations where the use would otherwise be an offence under the control-of-use legislation in the jurisdiction for which the permit is issued, i.e. Queensland. Following an assessment of the proposed use the APVMA was satisfied that the products could be used safely and issued a permit with specific

Question: 46 (continued)

conditions for use. Mixing of registered products in a tank mix is not an offence under Queensland control-of-use legislation, therefore the permit is not needed for that specific purpose.

The APVMA would need to issue a different permit to allow the uses specified in permit PER 11463 in other jurisdictions.

4. No. To be able to legally commercialise a chemical product under a tradename with specific pesticidal claims, it would first require assessment and registration in accordance with the requirements stated in the Agvet Code.

5. If a new chemical product was developed and legally commercialised, it would have to have been assessed by the APVMA for worker exposure and safety, among other things, as indicated in the response to part 4 above. Part of the assessment and registration process includes the setting of label instructions, such as safety directions, appropriate warning statements and for appropriate protective equipment to be worn during specific operations when using the product. The product label must be read and label instructions followed when using any pesticide product in Australia.

6. 'Gloricide' is not a registered chemical product. The department understands that it is a name used by some people to refer to a tank mix of registered chemical products approved for certain uses in Queensland under a permit. The MSDS in question was prepared to satisfy the relevant state WorkSafe authority. As such, it is inappropriate for the APVMA to provide specific comment.

7. Approved labels for registered products must contain adequate instructions for use as described in section 14 of the Agvet Code. Products of 2, 4-D and metsulfuron-methyl carry adequate instructions for use. If valid concerns regarding use of a product or chemical are raised, then the product and its label directions may be the focus of a targeted review to address the concerns raised.

   Under current legislation, there isn't a program to 're-register' or 're-approve' chemicals on a regular basis.

8. The permit (PER 10540) clearly states that the products included in the permit must be used in accordance with label directions. The wording in the permit is reproduced below:

   'THIS PERMIT provides for the use of a product in a manner other than specified on the approved label of the product. Unless otherwise stated in this permit, the use of the product must be in accordance with instructions on its label.'

   Permit PER 10540 includes an instruction, for observing a 20 metre buffer around waterways when using certain glyphosate products.

Question: 46 (continued)

9. The response to question 230 from Supplementary Budget Estimates October 2012 did not indicate that Australia is not a signatory to the enforcement component of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. Within Australia, the lead government agency responsible for the convention is the Australian Government Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC). The Department of Agriculture, Fisheries and Forestry (DAFF) and the APVMA assist DSEWPaC to meet the government's obligations under the convention in regards to pesticides.

10. Yes. However, to form 2,4,5-T from 2,4-D the conditions would have to achieve addition of a chlorine atom to the 2,4-D molecule, which is highly unlikely except under specialised laboratory conditions.

11. In Queensland, The Queensland Department of Agriculture, Fisheries and Forestry (QDAFF) is responsible for ensuring use of products in accordance with the conditions of use stated in the permit instructions.

12. The relevant state authority (Qld DAFF) is responsible for the enforcement of the permit conditions, label conditions and restrictions, as they relate to use of the products.

13. The Australian Government does not record this type of information.

14. Please see the response to question 12.

15. Any restrictions, e.g. 'setbacks', stated on the product label also apply to use under the permit, unless additional restrictions are stated in the permit. Please see response to question 8 above. Permits issued for use of registered products, specifically require those products to be used according to label instructions and restrictions.

16. Please see the response to question 12.

17. The uses allowed in permit PER10540 have been approved for a number of years and to date the APVMA has not received specific complaints through the adverse experience reporting program regarding adverse impacts to amphibians.

18. This is a matter for the offices listed in the question.

19. Yes. Mr Presnell does not have standing to request a statement of reasons for permit PER 11463 under the *Administrative Decisions (Judicial Review) Act 1977*. Mr Presnell was informed of the finding by letter dated 7 November 2012.

20. Mr Presnell made numerous complaints in 2012, through widely distributed emails, regarding the APVMA's CEO actions in relation to 'Gloricide'. DAFF and the APVMA have responded to Mr Presnell's complaints according to their responsibilities.

Question: 46 (continued)

21. See the response to question 20.

22. No. The APVMA conducted a compliance audit and found no breach of its requirements by the permit holder. Please also see the response to question 12 above.

23. It is proper for the APVMA to regulate to the extent of its jurisdiction. The APVMA is responsible for the regulation of labels and approves them based on as assessment of data required for registration purposes. Material Safety Data Sheets are managed between Safework Australia and the relevant state WorkSafe authority.

24. The high volatile esters of the herbicide 2,4-D have been suspended since October 2006. The current instructions as included in permit PER 13339 require 100m buffer zones and this applies to users in all jurisdictions.

25. No. The various questions posed in question on notice 231 from October 2012 and the respective responses do not make mention of '*standards on labels*'.

26. If the conditions of use under the permit have been breached, that is a matter for the relevant state Control-of-Use authority to investigate.

27. The permit has conditions in relation to the use of product formulations in aquatic situations, which include:

    "Only those specific products which have label approvals currently in place for aquatic use, may be used in or near aquatic areas"

28. Please see the responses to questions 12 and 22.

29. It is not appropriate for the APVMA to comment on matters relating to the SCRC claims. There are two permits that are current, PER 10540 and PER 11463. Both are held by Biosecurity Queensland (now QDAFF) and both are issued as minor use permits.

30. Please see the response to question 12.

31. The APVMA has no knowledge of the expertise of the SCRC staff.

32. The permit allows something that is otherwise an offence under state control of use legislation. The making of a tank mix is not an offence under state control of use legislation, unless product labels specifically prohibit mixing of one product with another. Where there is no label prohibition, the permit does not need to include tank mixing instructions.

33. This 'tank mix' of 2,4 D and metsulfuron that is referred to in permit PER 10540 specifies use with specific concentrations of chemicals, whereas the mix of above chemicals in permit PER 11463 is dependent on the specific use pattern. The risks under either permit are assessed as acceptable