Senate Rural and Regional Affairs and Transport Legislation Committee

Questions on Notice – Monday, 04 February 2013 Canberra, ACT

Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

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SENATE RURAL AND REGIONAL AFFAIRS AND TRANSPORT LEGISLATION COMMITTEE

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Public Hearing Monday, 04 February 2013

Questions Taken on Notice – WWF Australia and the National Toxics Network

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1. HANSARD, PG 7

Senator NASH: Thanks for the greyhound analogy—I feel like one! Mr Heath, you mentioned reviews before and you said that some of the reviews have been going on for decades. Which ones?

Mr Heath: The Diuron review that just finished went for 13 years. The review into Chlorpyrifos has been going for 17 years. Jo, help me out.

Ms Immig: Off the top of my head, it is difficult. The Chlorpyrifos inquiry has been going on for a long time.

Senator NASH: That is all right. Perhaps you could take that on notice for me, given that you indicated that there seems to be a number of them.

Mr Heath: Sure.

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Senator NASH: That is all right. Perhaps you could take that on notice for me, given that you indicated that there seems to be a number of them.

Mr Heath: Sure.

Response:

In response to Senator Nash's request, we provide the following examples of APVMA chemical reviews that are incomplete and have been ongoing for an unreasonable length of time. This list is not exhaustive.

There are other chemicals (not listed below) that were also nominated for review around the mid-1990s but no review process has even commenced for these chemicals.

This information was obtained from the APVMA's website Chemical Review pogram http://www.apvma.gov.au/products/review/a_z_reviews.php.

2,4-D (18 years)
Status: review in progress

In 1995 the APVMA began a review of 2,4-D because of concerns over its potential risk to public health, occupational health and safety, and the environment (including impacts on waterways, non-target animals and plants).

Azinphos-methyl (19 years)
Status: review in progress, pending spray drift review

In 1994 azinphos-methyl was nominated for review as part of the Existing Chemicals Review Program (ECRP). Azinphos-methyl was nominated due to concerns about its toxicity, and hence potential risks to the public and occupational health and safety, and the environment. There were related concerns about residues and possible impacts on Australian trade.

Chlorpyrifos (13years +)
Status: Review in Progress

The APVMA began a review of chlorpyrifos [NB date not specified but at least since 2000] because of concerns over its toxicity and the potential risks to worker health and safety and the environment.

Diazinon (17 years)
Status: review in progress

In December 1996 the APVMA (formerly the NRA) began a review of diazinon because of concerns over the potential for diazinon to form highly toxic breakdown products and its potential to pose a risk to public health, occupational health and safety, the environment, animals, and Australia's trade.

Fenamiphos (10 years)
Status: review in progress

In April 2003 the APVMA (formerly the NRA) began a review of fenamiphos because of concerns relating to public health, occupational health and safety, the environment, and residues in food. The review will provide the APVMA with information to enable it to determine whether the existing use of fenamiphos should continue in Australia. To date there have only been limited occupational health and safety assessments conducted for fenamiphos products in Australia.

Fenitrothion (19 years)
Status: review in progress

Fenitrothion was nominated for review because of concerns over worker health and safety and its potential to cause adverse environmental effects.

Fenthion (15 years)
Status: Review in progress

Fenthion was nominated for review in 1994 because of concerns about public health, occupational health and safety, the environment and food residues.

Fipronil (10 years)
Status: review in progress; scope extended to include consideration of environmental concerns—submissions for the extended review scope are open until 31 August 2012

Fipronil was nominated for review following the receipt of a number of reports of adverse experiences in humans and animals. In 2007 the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) nominated fipronil as a priority 1 chemical for environmental review. This followed the identification of new information, considered by international regulatory authorities (primarily the European Food Safety Authority in 2006), showing that fipronil and its metabolites are very highly toxic to organisms in the environment, particularly aquatic and terrestrial insects.

Macrolide (14 years)
Status: review in progress

In September 1999 selected macrolide antibiotics (kitasamycin, oleandomycin and tylosin) were nominated for review because of concerns over their efficacy and their possible contribution to the development of antibiotic resistance in human medicine. This action was based on advice from the Joint Expert Advisory Committee on Antibiotic Resistance (JETACAR) which identified antibiotics used as growth promotants and for prophylactic purposes in food-producing animals as warranting review.

Maldison (10 years)
Status: review in progress

In February 2003 the APVMA began a review of maldison because of concerns about its toxicity and human health and safety. The review will provide the APVMA with information to determine whether the existing uses of maldison should continue in Australia.

Methidathion (11 years)
Status: review in progress

In May 2002 the APVMA (formerly the NRA) began a review of methidathion which focused on the assessment of the toxicology of methidathion. In June 2002 the APVMA released the Methidathion Review Scope Document (PDF, 9.7Mb) which included a request for registrants of products containing methidathion to provide a list of all relevant toxicological studies held by them. In October 2005 the APVMA board agreed to extend the scope of the review to include worker safety, residue and dietary risk concerns.

Methiocarb (18 years)
Status: review in progress

In 1995 the APVMA began a review of methiocarb because of concerns over public health, occupational health and safety, residues, and the environment. In April 2005 the APVMA released the Methiocarb Preliminary Review Findings Report (PDF, 989kb). The APVMA proposed varying product labels and deleting some uses so that the continued use of methiocarb would not pose an undue hazard to the safety of the public and would not unduly prejudice Australian trade.

Molinate (10 years)
Status: review in progress

Molinate was nominated for review following reports that low doses of the chemical could cause irreversible damage to nerves (neuropathy) and interfere with the development of the foetus and the young (developmental toxicity).

Neomycin (11 years)
Status: review in progress

In March 2002 neomycin was nominated for review by the Victorian and New South Wales Departments of Primary Industry and the National Residue Survey (NRS) because of concerns that the use of oral, intramammary and injectable preparations of neomycin, in accordance with the registered use-pattern, could exceed the Australian Maximum Residue Limit (MRL). Neomycin residues exceeding the MRL posed a potential risk to human health through the consumption of meat and offal from treated animals, and a potential risk to Australian export trade with residues of treated animals being higher than the standards established for overseas markets.

Omethoate (18 years)
Status: review in progress

Dimethoate was nominated because of concerns over toxicology, occupational health and safety, residues and trade. This action was based on advice from the Office of

Chemical Safety and Environmental Health (OCSEH) (external site) that omethoate may pose an undue hazard to public health. OCS further advised that an assessment of omethoate was required in conjunction with the concurrent review of dimethoate. This is because omethoate is the metabolite of dimethoate and the use of dimethoate on crops may lead to residues of omethoate in treated produce.

Parquat (16years)
Status: review in progress

In 1997 the APVMA (formerly the NRA) began a review of paraquat because of concerns over the potential risk to occupational health and safety and the environment. The review will provide the APVMA with information to enable it to determine whether the registered use of paraquat should continue in Australia. The review is expected to take several years to complete. During this time, the APVMA will carry out a comprehensive assessment of all available scientific information.

Procymidone (9 years)
Status: review in progress

In December 2004 the APVMA began a review of procymidone because of concerns relating to human health, namely worker exposure and public exposure to residues in food. This was based on advice from the Office of Chemical Safety (OCS) following a scientific assessment that identified the potential for procymidone to cause birth defects in laboratory animals.

Sheep ectoparasiticides (14 years)
Status: review in progress

In 1999 the APVMA began a review of selected sheep ectoparasiticides because of concerns over the potential environmental, occupational health and safety, and trade risks from residues on treated wool.

Simazine & cyanazine (19 years +)
Status: Review has not yet commenced

The review will commence once preliminary work is completed to determine the scope of the review. Work to determine the scope of the forthcoming review of simazine/cyanazine is underway, including collation and organisation of data holdings by APVMA's advisory agencies (including DSEWPC and OCSEH). The review will commence once this preliminary work is completed. The timeframe for this work has not been fixed but the APVMA is satisfied that the work now underway is appropriate, as it will help ensure that the forthcoming review is appropriately targeted and will facilitate timely review outcomes.

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Public Hearing Monday, 04 February 2013

Questions Taken on Notice – National Toxics Network

Questions on Notice

Senator Colbeck undertook to send through information relating to his questions of WWF Australia and the National Toxics Network:

Just if you are interested – have conducted a search on EU pesticides web (*http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection*)

Of WWF's eighty 'banned' chemicals, at least 12 are registered for use in the EU including:

- *bifenthrin*
- *cyproconazole*
- *dazomet*
- *diclofop*
- *dithianon*
- *fenoxycarb*
- *fluometuron*
- *metaldehyde*
- *myclobutanil*
- *paclobutrazol*
- *prochloraz*
- *pyridaben*

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- *fenoxycarb*
- *fluometuron*
- *metaldehyde*
- *myclobutanil*
- *paclobutrazol*
- *prochloraz*
- *pyridaben*

Response:

The above list of chemicals has been cross-checked with the 2010 WWF/NTN list provided to you and against the current EU pesticides database. All of the chemicals listed above are on the 2010 WWF/NTN list as 'prohibited in the EU'. At the time the list was compiled in 2010 this was correct. These chemicals were not approved in 2010 in the EU by Decision 2008/934.

Subsequent to the preparation of the 2010 WWF/NTN list these 12 chemicals have been re-submitted for inclusion in the EU and were recently approved for a narrow range of uses in

specific areas of the EU. These are not EU-wide approvals; only uses which are supported by the data submitter have been approved.

The question arises whether there is adequate data in Australia to support the range of uses these 12 chemicals are approved for here?

We will update our 2010 list to reflect these changes and others, such as the subsequent listing of endosulfan on the Stockholm Convention on Persistent Organic Pollutants.

Bifenthrin
Date of approval: 01/08/2012 - Expires 31/07/2019
Application resubmitted for inclusion (Reg 33/2008).
Supported use in wheat, barley, oats, triticale, rye, ornamentals and head cabbage

Cyproconazole
Date of approval: 01/06/2011 – Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use in wheat

Dazomet
Date of approval: 01/06/2011– Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use in lettuce and strawberries and soil grown tomatoes

Diclofop
Date of approval: 01/06/2011 – Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use on cereals

Dithianon
Date of approval: 01/06/2011 – Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use on pome fruit and wine grapes

Fenoxycarb
Date of approval: 01/06/2011 – Expires 31/05/2021

Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use apples and pears

Flometuron
Date of approval: 01/06/2011 – Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use cotton in Spain and Greece

Metaldehyde
Date of approval: 01/06/2011 – Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use cereals (rye, oat, wheat, barely, triticale) and rape seed

Myclobutanil
Date of approval: 01/06/2011 – Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use table wine grapes

Paclobutrazol
Date of approval: 01/06/2011 – Expires 31/05/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use winter oilseed rape

Procloraz
Date of approval: 01/01/2012 – Expires 31/05/2021
Supported use cereals

Pyridaben
Date of approval: 01/05/2011 – Expires 31/04/2021
Initially non included by Decision 2008/934. Included as from 1 June 2011 following re-submission for inclusion according to Reg. 33/2008.
Supported use citrus and tomato

SENATE RURAL AND REGIONAL AFFAIRS AND TRANSPORT LEGISLATION COMMITTEE

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Questions Taken on Notice – Animal Health Alliance

1. HANSARD, PG 15

Senator HEFFERNAN: This is a little off the page, but while we have you here could you briefly explain to this committee where we are up to in veterinary science with what was going on in New Zealand with playing around with human genes in cows to do something to their milk? I think that is pretty scary. Are you briefed on that?

Dr Holdsworth: Fortunately I am not briefed on that. I will defer to my colleagues to see whether they are briefed on that.

Dr Chudleigh: Not from our point of view, no.

Senator HEFFERNAN: You do not know anything about it?

Dr O'Brien: No, sorry.

Senator HEFFERNAN: You do not know anything about it?

Dr O'Brien: It is a very specialised area.

Senator HEFFERNAN: It is a very specialised area. It is pretty scary that they are actually playing around with human genes in cows to do something to their milk. I think that is scarier than most things.

Dr O'Brien: From a biotechnology point of view that has been potentially a holy grail. I am not a biotechnologist; I am just a humble veterinarian. They have talked about modifying the genome to put antibodies, growth factors or things that humans need who have genetic deficiencies so that there may be a way where specialised milk is given to infants and things like that to overcome disease. As far as I know, that has not ever got to market. That is the limit of my knowledge there.

Dr Holdsworth: Chair, if I can indulge you, I would assume in that scenario that any end product—say genetically modified milk, let us keep it basic—if that scenario emerged in Australia the two regulators would have oversight on that.

There would be the Office of the Gene Technology Regulator itself and Office of Gene Technology Regulator and Food Standards Australia New Zealand would have oversight of the end product, whether it was fit for purpose as a food for consumption in Australia.

CHAIR: Senator Heffernan I think the doctors and Mr Adams have answered your questions. So rather than dwell on that very important issue—

Senator HEFFERNAN: Would it be possible to put it on notice to you to come back with a reflection on where it is all up to because it involves your type of people in New Zealand?

CHAIR: 'Your type of people in New Zealand'—do you mean doctors in animal health?

Senator HEFFERNAN: At least they are doctors of something.

Dr Holdsworth: Chair, we take that on board.

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2. HANSARD, PG 17

Senator HEFFERNAN: What is your position on the patenting of animal genes, gentlemen?

Dr O'Brien: It worries me, as it obviously worries you, that you are patenting things which are part of nature.

Senator HEFFERNAN: You blokes need to address that. The final thing is, and you can take this on notice, could you explain to this committee, for the purposes of this hearing, the inconsistency in chemical animal use, which is brought about by the decision now to have Russian eligibility on your vendor declaration as opposed to European eligibility.

CHAIR: You can take that on notice unless you wish to answer it now. It is probably easier to do it now.

Dr Holdsworth: Very quickly, this is a bigger issue. It is called export slaughter intervals—it is the risk managing of trade, which is an impost that has been put on the APVMA. It was never their intent when they were set up to manage trade and the position of our industry is that they should not do it. We have a regulator who makes decisions on science and now they are also expected to manage trade, which, as all of you know, is not a science based issue.

Senator HEFFERNAN: If you would give us a written response, that would be helpful.

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CHAIR: 'Your type of people in New Zealand'—do you mean doctors in animal health?

Senator HEFFERNAN: At least they are doctors of something.

Dr Holdsworth: Chair, we take that on board.

Answer:

The relevant information can be found at the web link below:

http://www.stuff.co.nz/business/farming/7756189/Allergy-free-milk-on-the-way

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Senator HEFFERNAN: If you would give us a written response, that would be helpful.

Answer:

In responding to your email of 07 February 2013 requesting Alliance responses to questions taken on notice from Senator Heffernan at the Senate inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, I now supply you with information relating to the Alliance activities with respect to Senator Heffernan's specific question relating to trade problem involving Russia.

The series of email correspondence included (below) in this email records that the Alliance is aware of the trade risk relating to Russia and that we have raised our specific concerns with the appropriate authorities within DAFF and we are awaiting their follow up response to us.

From: Cooper, Sue -TMAD
Sent: Monday, 17 December 2012 2:39 PM
To: Peter Holdsworth
Cc: Chell, Rosanna
Subject: RE: Russian delegation visitation to Australia [SEC=UNCLASSIFIED]

Hi Peter

Thanks for your email. We are currently talking to the different areas of DAFF to put together a response to your members questions. We hope to get back to you soon.

Kind Regards

Sue

From: Peter Holdsworth
Sent: Monday, 17 December 2012 8:59 AM
To: Cooper, Sue -TMAD
Subject: Russian delegation visitation to Australia

Hi Susan,

Your contact details have been offered by DAFF to me in relation to questions I have received from member companies of the Animal Health Alliance relating to antimicrobials and standards imposed on meat exports from Australia to Russia.

My member companies are enquiring specifically in relation to the permitted use/residues levels for the antimicrobial drug oxytetracycline in meat exported from Australia into Russia and any potential for bans by Russia subject to that countries standards. My member companies understand that a Russian delegation met recently with representatives of DAFF and that this issue among others was on the agenda.

Any advice or guidance you can offer would be appreciated.

On a similar note, any update you can offer in relation to the ractopamine issue relating to meat exports to Russia would also be welcome.

Regards

Dr Peter Holdsworth AM FAICD

Chief Executive Officer

Animal Health Alliance
SOLUTIONS FOR THE FUTURE

SENATE RURAL AND REGIONAL AFFAIRS AND TRANSPORT LEGISLATION COMMITTEE

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Questions Taken on Notice – Australian Forest Products Association

1. HANSARD, PG 24

Senator COLBECK: Mr Matthew, you talk in your submission about the issue of minor use, but forestry is a very specific use for the chemicals you use. What proportion of those utilised would be on minor-use permits?

Mr Matthew: I will take it on notice to find out exactly the amount for you, Senator Colbeck. I certainly see parallels with the mushroom growers group in that, because we are small users of chemicals, we have to use the minor-use system. Senator Ruston just highlighted the fact that cost is an issue in terms of the minor-use system and the uncertainty of the length of time it takes to get those minor-use permits. Both of those things make it difficult, but for a minor use you need that chemical in the first place as you do for those other uses. One of the issues we have is the suite of chemicals, which you use in broader agricultural pursuits and we use for minor uses in forestry, is shrinking. That is of great concern to us, because we do not use a lot of chemicals. In the later rotation age, trees themselves control the weeds, but if we do not get that weed control in the first five years it is devastating for plantation survival.

2. HANSARD, PG 27-28

Senator BACK: Would that be because you are in a food related production cycle rather than fibre as in the case of forestry products?

Mr Seymour: My understanding was it was a requirement and that is why we undertake it. I am not sure why that may have been required. But in a practical sense we want to know as an industry if there is an issue so that we can tell everyone in the industry what that problem is and so that we can take steps to overcome it. But, touch wood, we have not had an adverse report to this point.

Senator BACK: Mr Matthew, could you provide us some advice?

Mr Matthew: I think it is probably outside my expertise in terms of the APVMA relationship. From state level, there is a lot of reporting that plantation growers

and forest managers need to do in regards to pesticides. I could take on notice the formal reporting back to APVMA.

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[Response] The forestry industry uses relatively small amounts of agvet chemicals as compared to other agricultural sectors (<0.5% of the total chemical pesticide spend in Australia).

However, chemical use is critical in the tree-crop establishment phase in terms of survival and weed competition control, and subsequently in the tending and maintenance phase in order to maintain and improve tree productivity.

Chemicals are used under APVMA registered labels or via APVMA permits (minor-use and other). The majority of forestry chemical use is on-label with a small percentage used via APVMA minor-use and other permits. This percentage varies between States and commercial businesses, due to different chemical uses, weeds and pests and spray situations so it is difficult to accurately quantify.

Although chemical use via permit is relatively small, it is a very important component of overall chemical use in forestry applications. It is often the case that minor use and/or other permits proceed registration, approval and on-label use of that chemical.

The importance of minor use and other permits for forestry applications is highlighted in situations where:

- **The forest industry utilise an existing permit in small scale trial situations to assess the potential and determine application rates for new chemicals (most of which are already utilised overseas);**
- **the application of existing chemicals (herbicides, pesticides and fungicides) for other agricultural uses is on- label but the forestry application is not yet included on the label (i.e. copper oxychloride to control the pine fungal infection dothistroma);**
- **emergency permits for the chemical control of new pests/diseases (i.e. fungicide for the Myrtle Rust incursion in 2010);**
- **forestry use of the chemical requires a higher application rate than the agricultural uses on the existing label; or**
- **the chemical is applied differently in the forestry use (i.e. may be on a label via boom-spray application but not aerially by helicopter).**

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2. HANSARD, PG 27-28

Senator BACK: Would that be because you are in a food related production cycle rather than fibre as in the case of forestry products?

Mr Seymour: My understanding was it was a requirement and that is why we undertake it. I am not sure why that may have been required. But in a practical sense we want to know as an industry if there is an issue so that we can tell everyone in the industry what that problem is and so that we can take steps to overcome it. But, touch wood, we have not had an adverse report to this point.

Senator BACK: Mr Matthew, could you provide us some advice?

Mr Matthew: I think it is probably outside my expertise in terms of the APVMA relationship. From state level, there is a lot of reporting that plantation growers and forest managers need to do in regards to pesticides. I could take on notice the formal reporting back to APVMA.

[Response] Significant scientific information (phytotoxity, efficacy, health and safety, and environmental effects) is required by APVMA from chemical registrants to initially approve and register a chemical. There is not a mandatory APVMA/national requirement for reporting by end-users on use of registered chemical pesticides. There is a voluntary program for the

reporting of adverse experiences with use of agvet chemicals to either APVMA or the chemical registrant called the adverse experience reporting program.

Control of use is managed by the States and land/forestry managers do have recording responsibilities under State regulation (e.g. NSW EPA requirement for a record of pesticide use under NSW Pesticide regulations). Further, many have structured voluntary monitoring processes (e.g. Tasmanian and NSW chemical monitoring processes).

SENATE RURAL AND REGIONAL AFFAIRS AND TRANSPORT LEGISLATION COMMITTEE

Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Public Hearing Monday, 04 February 2013

Questions Taken on Notice – Department of Agriculture, Fisheries and Forestry

1. HANSARD, PG 55

Senator NASH: Would you provide on notice exactly how that will operate so we have it very clearly to clarify that misunderstanding that obviously exists.

Mr Kelly: We can. It is explained in the explanatory memorandum.

Senator NASH: I know, but I just asked you.

Mr Koval: We can certainly provide that on notice. The second thing is something that I am sure you will get to in your question. You and Senator Colbeck have both gone to the reregistration scheme and what that means for chemicals that are out of intellectual property protection. I wanted to make a distinction between the reregistration scheme and the chemical review scheme. The reregistration scheme is a scheme that operates to filter the entire chemical inventory on the market and decide whether a chemical needs to be reviewed or. So the system is relatively simple. It assesses whether there are any reasonable grounds for doubt that the product would not meet the safety criteria, the trade criteria or the efficacy criteria.

2. HANSARD, PG 58

Senator NASH: I do apologise that my highest priority over summer was not the APVMA. I ask you to take on notice for me the clarification of those figures and what has actually changed. You are saying that $8 million figure is incorrect: what are you basing it on, what are the changes that predicate that?

3. HANSARD, PG 60

Senator BACK: You heard the question asked: in the event that the registrant for that chemical is not part of the process, they have not given their authority for it to be used, APVMA has decided, for whatever reason, extra to label conditions, that that chemical can be used in a minor application—mushrooms or forest products.

Where does the legal liability rest if a person purchases that chemical, uses it under the conditions for use approved by APVMA without the registrant being involved? If somebody is aggrieved or found to be commercially disadvantaged, to whom do they direct their lawyers?

Mr Koval: I will have to take that one on notice and take some advice. I am not a lawyer.

Department of Agriculture, Fisheries and Forestry

Committee inquiry: Senate Rural and Regional Affairs and Transport Legislation Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012
Date Held: 4 February 2013

Question Taken on Notice

Senator Nash asked officers appearing as witnesses at the Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 hearing held on 4 February 2013 the following questions which were taken on notice:

Senator NASH: Would you provide on notice exactly how that will operate so we have it very clearly to clarify that misunderstanding that obviously exists.
Mr Kelly: We can. It is explained in the explanatory memorandum.
Senator NASH: I know, but I just asked you.
Mr Koval: We can certainly provide that on notice.

Answer:

Item 32 of Schedule 1 of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 would insert new section 11 into the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). This section requires the APVMA complete a preliminary assessment of an application for approval or registration within one month of the application being lodged and advise the applicant within 14 days of the decision being made as to whether the application has passed preliminary assessment or whether it has refused the application. The same preliminary assessment process would also apply to applications for variation and for permits (under sections 27 and 110).

The APVMA is not to refuse the application only if it has not finished its preliminary assessment in the one month timeframe. It is extremely unlikely that a court would interpret the provision drafted for section 11 to require the APVMA to refuse an application if the APVMA has not completed the preliminary assessment within one month. Subsection 11(1) is a standalone requirement. Subsection 11(3) follows the conditional 'if' in subsection 11(2) and therefore qualifies that subsection. Further, new section 6D of the Agvet Code (proposed to be inserted by item 28 of Schedule 1 of the Bill) makes clear that the failure of the APVMA to do something within a specified timeframe does not invalidate the thing done.

In conducting a preliminary assessment the APVMA only needs to determine if the application appears to meet the application requirements. The preliminary assessment is not a technical assessment where the APVMA must be satisfied that the application meets the application requirements as this is dealt with in new section 14 (or section 29 or 112). The purpose of the preliminary assessment is to provide for an administrative check of the application. The APVMA must refuse applications that appear inferior or deficient at preliminary assessment so that it completes a full assessment only of applications that appear to be of the required standard.

Department of Agriculture, Fisheries and Forestry

Committee inquiry: Senate Rural and Regional Affairs and Transport Legislation Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012
Date Held: 4 February 2013

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Senator NASH: I do apologise that my highest priority over summer was not the APVMA. I ask you to take on notice for me the clarification of those figures and what has actually changed. You are saying that $8 million figure is incorrect: what are you basing it on, what are the changes that predicate that?

Answer:

The APVMA's 2012 cost recovery impact statement (CRIS), covering the period 1 July 2013 to 30 June 2015, forecasts increases in APVMA expenditure associated with the roll-out of the reform agenda. Please see the CRIS expenditure forecasts in the table below.

Expenditure forecasts from the 2012 APVMA CRIS (extract):

	2013–14 ($)	**2014–15 ($)**
Income	31 858 702	32 108 655
Less:		
Repayment of $2 million to government	(1 500 000)	-
Total Income	**30 358 702**	**32 108 655**
Expense—Base	30 162 593	30 811 649
Add:		
Implementation of Reform Agenda	2 344 482	-
Increase compliance and enforcement activities	771 338	814 289
Re-registration and re-approval scheme (on-going operation)	574 555	1 230 734
Total expenses	**33 852 968**	**32 856 672**
Surplus/(deficit)	**(3 494 266)**	**(748 017)**
Equity	**7 629 897**	**6 881 880**

After an initial increase in expenditure in 2013-14 to support implementation of the reforms, the ongoing additional costs of implementing the reforms are $2 045 023 in

2014-15 (compared with 2012-13). This one-year figure includes costs associated with an increased compliance and enforcement effort ($814 289) and assessing applications for re-registration and re-approval ($1 230 734).

In its 2010 mid-year economic and fiscal outlook statement, the government announced $8.8 million funding over four years to support the implementation of the proposed reforms.

Department of Agriculture, Fisheries and Forestry

Committee inquiry: Senate Rural and Regional Affairs and Transport Legislation Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012
Date Held: 4 February 2013

Question Taken on Notice

Senator Back asked officers appearing as witnesses at the Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 hearing held on 4 February 2013 the following questions which were taken on notice:

Senator BACK: You heard the question asked: in the event that the registrant for that chemical is not part of the process, they have not given their authority for it to be used, APVMA has decided, for whatever reason, extra to label conditions, that that chemical can be used in a minor application—mushrooms or forest products.
Where does the legal liability rest if a person purchases that chemical, uses it under the conditions for use approved by APVMA without the registrant being involved? If somebody is aggrieved or found to be commercially disadvantaged, to whom do they direct their lawyers?
Mr Koval: I will have to take that one on notice and take some advice. I am not a lawyer.

Answer:

To the Department of Agriculture, Fisheries and Forestry or the APVMA's knowledge, this matter has not been explored in the courts. There are laws that generally deal with product liability, for example, the *Competition and Consumer Act 2010*, but other remedies may also be available through other civil proceedings.

Determining liability is a complex matter and it is recommended that people seek independent legal advice about their particular situation. In general terms any liability will depend on the particular facts in each specific circumstance and any steps that parties may have taken to reduce their exposure to liability.

SENATE RURAL AND REGIONAL AFFAIRS AND TRANSPORT LEGISLATION COMMITTEE

Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Public Hearing Monday, 04 February 2013

Questions Taken on Notice – Australian Pesticides and Veterinary Medicines Authority

1. HANSARD, PG 60

Senator BACK: Working as you do closely with other countries, what other countries require or in fact publish an application summary in advance at the beginning of the application process? Could you take that on notice?

Dr Bhula: I can briefly explain what the US EPA does. It will publish a notice in what is called its Federal Register, which is the equivalent of our Gazette. All it contains is a summary of the company, what they have applied for, whether it is going to be used on a food crop and then there is a reference or a set of contact details. That is currently with US EPA undertakes. We could take your question on notice in terms of the European regulatory system.

Senator BACK: I would be very appreciative and thank you very much for the advice, Dr Bhula. What I would be particularly interested in knowing is, in Australia what more, if any, information is required in that application summary than is required in other countries because I could also be thinking about competitors from overseas? If I may go to another topic, Mr Kelly, I think you explained as part of the amendments that there will be an electronic process now so that if somebody fails to put in a date or whatever they cannot proceed with the application. That sounds to me to be an action that would remove or eliminate a lot of these processes which seem to frustrate everybody at the moment, so I applaud you on that.

If I may go back, you heard the questions and answers earlier to do with APVMA allowing the use of the registered chemical under conditions, presumably to a third party, different from the label conditions for which the registrant has approval. You can correct me but I understand that the registrant of the chemical does not have to be part of the process. Is that correct?

2. HANSARD, PG 61

Senator BACK: Can I ask why APVMA itself does not undertake that evaluation process?

Mr Matthew: It was a decision made by government at the inception of the scheme. I would have to research it further and take it on notice if you want more information.

3. HANSRAD, PG 61

Senator BACK: So what mechanisms are in place then to actually protect the party that contracts to the evaluator and indeed the manufacturer against leakage of information that may come from the evaluator to a competitor or for whatever purposes? What assurances can you have in that event? Let us say the process fails and the evaluator brings in an adverse report and you decide you are not going to register that chemical. There would be tremendous commercial loss to the company. And then at some time in the future, by miraculous coincidence, somebody else comes along and gets a chemical registered along very similar lines with similar base products. How do you protect yourselves and ultimately the applicant from that abuse of process?

Mr Matthew: I understand there are very strong conflict-of-interest guidelines and requirements. We also have a collaborative arrangement with the TGA that some of their auditors will also conduct audits when they are concurrently at the premises. If you require further detail then I could take it on notice.

APVMA

Committee inquiry: Rural and Regional Affairs and Transport inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012
Date Held: 4 February 2013

Question Taken on Notice

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Answer:

The application summaries published by the APVMA contains information about the applicant, the chemical product and the uses proposed in the application, as well as a list of the data submitted to support the application. Comparatively, APVMA summaries are broader than the summaries published by the United States Environment Protection Agency (USEPA), but less detailed than those by the European Food Safety Authority (EFSA).

The USEPA publishes a notice of receipt of pesticide applications, which contains information about the applicant, the chemical product and the uses proposed in the application. The EFSA publishes summary dossiers for applications for new active substances under Regulation (EC) No 1107/2009, which include information about chemical products and proposed uses, summaries of the results of studies and details of the data owner and of the person or institute that developed the data.

Application summaries were introduced in Australia in 2005 as a transparency measure to compliment the data protection measures introduced in the *US Free Trade Agreement Implementation Act 2004*. This measure benefits industry primarily through increasing the transparency of decision-making and stimulating access to protected information by potential competitors under reasonable market conditions.

APVMA

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Senator BACK: Can I ask why APVMA itself does not undertake that evaluation process?
Mr Matthew: It was a decision made by government at the inception of the scheme. I would have to research it further and take it on notice if you want more information.

Answer:

The third party model of external auditing of the manufacturers of veterinary medicines in Australia predates the National Registration Scheme (NRS) for which the APVMA was created. After the NRS commenced in 1993 the third party model was formally adopted via resolution during the seventeenth meeting of the Governing Board of the then National Registration Authority (NRA), 19-20 September 1995.

APVMA

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Senator BACK: So what mechanisms are in place then to actually protect the party that contracts to the evaluator and indeed the manufacturer against leakage of information that may come from the evaluator to a competitor or for whatever purposes? What assurances can you have in that event? Let us say the process fails and the evaluator brings in an adverse report and you decide you are not going to register that chemical. There would be tremendous commercial loss to the company. And then at some time in the future, by miraculous coincidence, somebody else comes along and gets a chemical registered along very similar lines with similar base products. How do you protect yourselves and ultimately the applicant from that abuse of process?
Mr Matthew: I understand there are very strong conflict-of-interest guidelines and requirements. We also have a collaborative arrangement with the TGA that some of their auditors will also conduct audits when they are concurrently at the premises. If you require further detail then I could take it on notice.

Answer:

There are a range of controls in respect of auditors and other external parties who conduct audit or assessment activities for the APVMA.

All the arrangements specifically recognise that the inappropriate disclosure of confidential commercial information is a criminal offence that can attract criminal penalty of imprisonment for 2 years. The arrangements also contain rigorous 'conflict of interest' provisions that the APVMA reinforces with auditors and external parties every time they are engaged to perform services.

APVMA

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Senator BACK: Thank you. In providing that, I would be appreciative, without you having to go to too much effort, if you would appraise me of what happens in other countries and continents—the United States, Canada, Europe and the UK—in that line.

Answer:

In the United States, Canada, Europe and the UK the Good Manufacturing Practice auditors for veterinary medicines are employed directly as staff members of the relevant national regulator. Review of audit reports submitted to the national regulator and consequential licensing decisions are conducted by the staff of those regulators, which corresponds to the Australian practice.