Senate Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2009

Agriculture, Fisheries and Forestry

Question: APVMA 01

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Disclosure of Confidential Commercial Information
Hansard Page 10 (27/10/2009)

Senator Back asked:

Senator BACK—You have had some allegations levelled at you in the media, and in other sectors, of
dysfunction. That relates, of course, to the regrettable disclosure of confidential commercial information about product formulation to competitors. I understand that the party affected by this was only advised in August 2008 that that occurred and yet that occurred back in 2007. Could you explain why there was a delay of 12 months before you advised that company?
Dr Bennet-Jenkins—There are a number of processes that we need to go through in terms of advising the person whose information was disclosed. The first step is to get assurance from the person who has received the information that they will not use that information. In this case, because there were applications in process involved that had not actually been accepted for evaluation, their existence was considered to be commercially in confidence. It was a complicated step of getting the authority from the various players in order to be able to speak with the other players. That was a process that we had to go through before we were able to contact the person.
Senator BACK—Did you establish where in the organisation this error or negligence occurred? Have you reviewed that and established it?
Dr Bennet-Jenkins—Yes. We did a full audit at the time when it occurred. That audit showed that it was one particular individual who inadvertently in writing letters disclosed information that should not have been disclosed. That person is no longer at the APVMA and we have put things in place. We have had a second audit. That audit has brought good results in terms of the processes we have put in place, which includes peer review of all letters that are written to applicants, in terms of information we need from them, and that continues. We have senior people oversighting the more junior staff in terms of the letters that they write.
Senator BACK—Just turning to the comment you made a moment ago in terms of establishing
communication with the competitors, the allegation was made that in fact a bullying letter was sent to the competitor's registration consultant threatening even a jail term of up to two years if they disclosed it. Would you care to comment on that? Is that wide of the mark?
Dr Bennet-Jenkins—The basis to that is that the provisions in our legislation in terms of disclosure of commercial-in-confidence information actually has the provision for the penalties that might apply if that information is used. An important step is to get the assurance from the person who has received the information that they will not use it.

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Question: APVMA 01 (continued)

Senator BACK—Presumably the person who left the agency would have also been facing the threat of two years jail in that particular circumstance?
Dr Bennet-Jenkins—Certainly, yes.
Senator BACK—Obviously having left the agency they then were not likely to be liable to that threat of a jail term?
Dr Bennet-Jenkins—Perhaps I can take on notice the actual legal legislative procedures that would apply in this case.

Answer:

Section 162 of the Agvet Code applies to current and former staff of the Authority.

Section 162 carries a maximum offence of 2 years imprisonment. It covers direct and indirect disclosure of any information about a chemical product that the person knows was confidential commercial information and was acquired by them in the performance of their duties or exercise of powers.

To be guilty of an offence against section 162 a person would need to have the deliberate intention to disclose the information or be reckless about the disclosure. Our investigation showed that the staff member in question had no deliberate intention to disclose the information. The disclosures were inadvertent in that it is clear from the relevant product files that in assessing whether one chemical product was closely similar to another, the staff member thought it appropriate to tell an applicant why their chemical product was not closely similar.

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Agriculture, Fisheries and Forestry

Question: APVMA 02

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Imtrade litigation
Hansard Page: 11 (27/10/2009)

Senator Back asked:

Senator BACK—Thank you. I would appreciate that. I turn now to a Western Australian crop chemical company called Entrade. Again, there have been accusations levelled at the authority due to a claim that the APVMA had unlawfully deregistered the products. Would you care to give us some understanding as to where that circumstance is? Was that the case and could you explain the background to it?
Dr Bennet-Jenkins—The background to that information is that we received information to indicate that Entrade had registered products based on false information. We did some investigations and, given that the registrations were based on false information, took the step to consider those decisions to have been invalid. That was challenged at the AAT and then also to the Federal Court, where it was determined that the APVMA should not have made that decision to take the products off the register on its own. It should, at first, have received advice through the courts in terms of whether we should do so.
Senator BACK—Can you tell me how the processes and procedures have changed in the authority to
ensure that you do not have a repeat of that circumstance?
Dr Bennet-Jenkins—Of having false information being received?
Senator BACK—Yes.
Dr Bennet-Jenkins—The registration system is a paper based trust based system. We are now working with the chemicals that are imported from other countries from the importing countries with the regulatory authorities there to be able to verify and check sources of chemicals that are claimed on application forms in that way and we are also being much more stringent in terms of verifying the authenticity of the paperwork that is submitted to us.
Senator BACK—Is it available, too, as to the level of the settlement and the legal fees incurred?
Dr Bennet-Jenkins—We will take that on notice.

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Question: APVMA 02 (continued)

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) incurred $572,671 in legal fees, which covers the Administrative Appeals Tribunal proceedings and three related Federal Court proceedings. The APVMA paid $75,000 towards Imtrade's costs in compliance with decisions of Justice Gilmour that the APVMA pay Imtrade its legal costs.

The costs can be partly attributed to the high workload that the litigation placed upon the APVMA, including the production of numerous documents to the Court at Imtrade's request and a large amount of affidavit material. The legal proceedings spanned almost two years and involved more than 100 products.

The litigation between the APVMA and Imtrade was settled on the basis that included Imtrade providing the APVMA with accurate information about the manufacturing source of its chemicals and submitting to audits aimed at verifying those sources. The APVMA agreed it would amend the corresponding entries on its Record of Approved Active Constituents or Register of Chemical Products. If Imtrade did not provide the required information, then the APVMA would remove the relevant entries from its Record or Register.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: APVMA 03

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Keeping farmers informed about the assessment of endosulfan
Hansard Page: 11-12 (27/10/2009)

Senator Milne asked:
I wanted to ask about Endosulfan. I read an article this week suggesting that it has come closer to being listed as a persistent organic pollutant under the Stockholm convention. What is Australia's position in relation to it? Were you in attendance at that recent meeting? Can you update the committee in relation to that matter?
Dr Bennet-Jenkins—Certainly. It is actually the responsibility of the department in terms of providing input to the Stockholm convention. I might pass to my colleague to comment on that. I can give you some information that the department certainly was there at the Stockholm convention and participated at the meeting.
Mr Glyde—The convention POPs review committee met from 12 to 15 October and has agreed to undertake the second phase of a three-phase process for assessing the risk profile of endosulfan. The work plan is being developed and it will be considered under the third phase at the next meeting of the Persistent Organic Pollutants Review Committee in October 2010. They undertake that review before they make a recommendation to the conference of the parties for chemicals to be listed under the convention. I am advised that the earliest Endosulfan could be listed is May 2011.
Senator MILNE—Given that there is a reasonable probability at this stage since it has entered the second phase of the assessment that it may well be listed in 2011, what action is the department taking to keep Australian farmers informed about the process, because as I understand it this is a fairly widely used pesticide?
Mr Glyde—I would have to take that on notice. I am not quite sure what processes we have for keeping farmers informed about that. I am really not quite sure of the exact methods we use to do that.
Senator MILNE—Could you just inform me if you have anything?
Mr Glyde—Yes.

Answer:

DAFF liaised with the Australian registrants of endosulfan prior to meetings of the Stockholm Convention's Persistent Organic Pollutants Review Committee (POPRC) in 2007, 2008 and 2009.

If the POPRC recommends to the Convention's Conference of the Parties (COP) that endosulfan should be listed, it is expected that a regulatory impact statement would be prepared and stakeholders, including farmer groups, would be consulted prior to the meeting of the COP, scheduled for May 2011.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: APVMA 04

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Atrazine
Hansard Page: 12-13 (27/10/2009)

Senator Heffernan asked:

Senator HEFFERNAN—I want to ask a question about that particular family of chemicals. I do not want to do a commercial ad here, but why have we not moved to the next generation of pesticides? The atrazine family of chemicals is old-fashioned now. One of the problems in Tassie, as with elsewhere, is that it is a large particle chemical that they put on at double the rate because it does not have the residual effect that the new generation of chemicals has. Why the hell are we using it? There is a new generation of chemicals. If you do not know about it, go and ask someone. There is no need to use this. It is a deadhead policy.
Dr Bennet-Jenkins—Yes.
Senator HEFFERNAN—I do not know whether it explains the double-headed Tasmanian thing.
CHAIR—That comment was probably not called for whilst pointing to one of your colleagues. You might think it is hilarious at other times. We are running very short of time. Senator Colbeck has probably one question.
Senator HEFFERNAN—Are you aware of the new generation?
CHAIR—Senator Heffernan, we are running to a very tight schedule, with the indulgence of the rest of the
committee—
Senator HEFFERNAN—I will put that on notice.
CHAIR—Yes, put that on notice.
Senator HEFFERNAN—And he can go and find out.
Dr Bennet-Jenkins—I will do that.

Answer:

The agricultural and veterinary chemicals legislation under which the Australian Pesticides and Veterinary Medicines Authority (APVMA) operates gives the APVMA the power to cancel approvals and/or registrations of chemicals where there are concerns regarding their safety or efficacy. The legislation does not provide for the cancellation or phasing out of older chemicals where newer generation of chemicals with different risk profiles become available.

The APVMA has recently extensively reviewed atrazine and taken regulatory action to restrict its use. The APVMA has no evidence that atrazine is likely to be hazardous or harmful to people or the environment under the current conditions of use. The APVMA is continuing to review new information on atrazine as it becomes available and will take regulatory action should this information raise new, previously unknown concerns about the safety of on-going use.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: APVMA 05

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Endosulfan
Hansard Page: 13 (27/10/2009)

Senator Colbeck asked:

Senator COLBECK—What are the major agricultural uses for Endosulfan in Australia? Can you give us a sense of the volume that is used?
Dr Bennet-Jenkins—The approved uses, I would have to say, for Endosulfan are cotton, canola and vegetables mostly and some tree crops, such as citrus, mangoes, pome fruits, avocadoes, macadamias and some vine crops. I am unable to give you the volume of use. We do not collect the volume of use data, but I understand the volume of use has dropped considerably in the last few years particularly in terms of the greater use of genetically modified cotton crops.
Senator COLBECK—What is the key use in Tasmania?
Dr Bennet-Jenkins—I would have to take that on notice. I am not sure.

Answer:

Endosulfan is registered for use in the following crops/situations in Tasmania, as well as other States:

Early pre-emergent use only in oilseeds and pulse crops; beetroot; cabbage, cauliflower and broccoli; capsicums; celery; pumpkin, melon, marrow, squash; eggplant; potato; tomato; passionfruit; apple and pear.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: APVMA 06

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Atrazine
Hansard Page: Written

Senator Abetz asked:

1. Is it APVMA's view that atrazine is an endocrine disruptor which may affect humans? If not, what is APVMA's view?
2. Given the fact that the US EPA has launched a comprehensive re-investigation of the health impacts of atrazine and that APVMA has also decided to re-examine more recent studies on the issue, when it is anticipated that the examination will be complete?

Answer:

1. Based on available evidence to date and expert advice from the Department of Health and Ageing, the Australian Pesticides and Veterinary Medicines Authority (APVMA) risk assessment concluded that the use of atrazine in Australia, as approved, is unlikely to affect endocrine systems or cause adverse effects resulting from perturbations of endocrine mechanisms in humans.

   The Office of Chemical Safety and Environmental Health (OCSEH), within the Department of Health and Ageing, conducts human health assessments of both agricultural and veterinary chemicals and provides advice to the APVMA. Similarly, the Department of the Environment, Water, Heritage and the Arts (DEWHA) conducts ecotoxicity assessments for the APVMA. For pesticides, a large battery of toxicity tests (see last paragraph) is used to find the lowest dose at which no adverse effect is seen – this is called the No-Observed Effect-Level (NOEL) level and is most commonly derived from studies in the most sensitive test species. Then a safety factor (usually 100) is applied to establish a conservative value for a human health intake value.

   In a previous response to Senate Estimates questions on atrazine (May 2009), the APVMA stated that the effects of atrazine (including its neuro-endocrine effects) are not a problem for human health at levels to which people might be exposed from its approved uses.

Question: APVMA 06 (continued)

The fundamental principle of chemical risk assessment is that risk is a function of hazard and exposure. Thus:

Risk = Hazard (ie. the intrinsic toxicity of the chemical) x Exposure

Chemical assessment takes into account the toxicity of the chemical being considered and the potential for people (or environmental species, if conducting an ecotoxicity assessment) to be exposed to the chemical. Exposure may occur either from using/apply product, or from being exposed to chemical residues in food from treated crops or food-producing animals. In 2008 the APVMA concluded that atrazine can be used safely and effectively when used in accordance with the label instructions.

A related conclusion was made by the World Health Organization (WHO) in its 2007 review of atrazine. Its Joint Meeting on Pesticide Residues (JMPR) established an Acceptable Daily Intake (ADI) based on a neuro-endocrine effect of atrazine. It concluded that this exposure value, established using a 100-fold safety factor, was "protective for the consequences of neuroendocrine and other adverse effects caused by prolonged exposure to atrazine and its chloro-*s*-triazine metabolites".

The APVMA notes that the Australian ADI is four-fold lower (ie. four-times more conservative) than the value established by the WHO in 2007.

A summary of the JMPR assessment may be found at:- http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2007_rep/Atrazine.pdf.

2. In March 2008 the APVMA published the final report on the Australian atrazine review; further regulatory actions were taken as part of the finalisation of this review followed extensive regulatory control actions taken by the APVMA in 1994 and 1997, including the phase-out of all industrial and domestic uses of atrazine. Additional label instructions which were implemented at that time were intended to reduce the risk of atrazine entering waterways at potentially harmful concentrations.

Question: APVMA 06 (continued)

New and emerging research continues into the biological and biochemical effects of atrazine. Therefore, in addition to finalising the main aspects of the atrazine review, the APVMA initiated a project to re-examine the possibility that the triazines (atrazine and related chemicals) may have previously unreported biological effects, taking into account ongoing research. This work commenced in mid-2008 when the APVMA commissioned the Office of Chemical Safety and Environmental Health (OCSEH) in the Australian Government Department of Health and Ageing to consider emerging research on the biochemical actions of atrazine published since 2004.

The APVMA will publish the report once it has been finalised.

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Question: APVMA 07

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Atrazine
Hansard Page: Written

Senator Abetz asked:

1. Is it the APVMA's view that mixing atrazine with other chemicals, including wetting agents, before spraying may increase toxicity?

2. If Yes, to what extent and what is APVMA's view about banning the use of such mixtures until it has reached a view about whether such mixtures may harm human health?

3. If the answer is No, on the basis of what research and findings has APVMA formed this view given?

Answer:

1. It is unlikely that mixing with other chemicals would significantly increase the toxicity of atrazine to animals and humans other than the individual toxicity of each chemical involved. At the exposure levels from prescribed use practices, any risk would be well below the set health standards.

2. N/A

3. Targeted studies testing mice continuously exposed over two generations to atrazine mixed with a number of other common pesticides and fertilizer found no significant health effects, even at exposures 100 times greater than groundwater levels of atrazine found in the US. (APVMA Atrazine Review – 1997; Technical Report Toxicology Assessment - see http://www.apvma.gov.au/chemrev/downloads/atrazine_tox.pdf). Similarly no effects were seen at these same doses in a rat teratology (birth defects) study, or in general toxicity studies in mice and rats, or in a number of genotoxicity tests in mice and rats. Mixtures of atrazine plus various other pesticides and inert ingredients did not produce liver cancer in a short-term model for liver cancer in rats.

   Evidence obtained so far from studies of chemical mixtures and the large safety margin built into health standards of exposure for each individual chemical indicates that it is not likely to result in a measurably increased risk to justify regulatory action.

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Question: APVMA 08

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Aerial Spraying
Hansard Page: Written

Senator Abetz asked:

1 Does the APVMA undertake compliance monitoring for aerial spraying to confirm that its modelling for aerial spraying is correct?
   (a) If so, what are the findings from that monitoring?
   (b) What is APVMA's view about those findings?
2 Is the APVMA satisfied that the rules/guidelines established for aerial spraying agricultural chemicals are
   (a) adequate to protect human health; and
   (b) complied with?
3. Is it the APVMA's view that there should be a national competency scheme to certify aerial sprayers?
4. If so, what steps has APVMA taken to achieve such a scheme, and when did they take them?

Answer:

1. Compliance with instructions for use is the responsibility of the states and territories.
   The Australian Pesticides and Veterinary Medicines Authority (APVMA) operates an adverse experience reporting program to stay informed of problems that may arise from pesticide use, and it maintains close ties with the state/territory authorities that control the use of pesticides to be aware of specific enforcement activities.
   The APVMA does not conduct environmental monitoring although it may require registrants to do so as part of a registration or chemical review data package.
   The validity of the spray drift aerial modelling is thoroughly established and internationally accepted. The studies that validated the modelling approach were very thorough and scientifically sound and are relevant to equipment and methods used under Australian conditions.

Question: APVMA 08 (continued)

2. The APVMA is satisfied that its risk assessment approach adequately assesses risk and provides regulatory protections for the community and the environment. Over the last six years the APVMA has continuously refined its methods and is now engaged in applying those refinements to new products and particularly to older products that need to have their labels updated. The APVMA's overall approach to spray drift risk regulation can be found on its website in the APVMA Operating Principles in Relation to Spray Drift Risk. The APVMA website also contains much other information about how it assesses spray drift risk.
The aerial agriculture industry has been improving its practices significantly over the last decade, partly in response to new regulations by the APVMA and partly due to a growing recognition within the industry of the importance of best practice. Improved technology, including GPS, onboard real-time wind speed and direction monitoring, easily available satellite photography, pre-application risk assessments and better record keeping.

   Stronger restrictions were recently introduced to labels by the APVMA. These will give state/territory authorities greater enforcement powers against careless operators. The new restrictions apply to all new chemicals and are being applied to existing chemicals through a chemical review process. Compliance with instructions for use is the responsibility of the states and territories. The APVMA maintains close ties with state/territory control-of-use authorities to be aware of specific enforcement activities.

3&4. State and territory governments are responsible for licensing pilots and businesses to ensure they are competent to apply agricultural chemicals by air. The Aerial Agricultural Association of Australia operates the SpraySafe program that accredits people involved in the aerial application of agricultural chemicals.

   The Primary Industries Ministerial Council (PIMC) has been directed by COAG, as part of its response to the Productivity Commission Report on Chemicals and Plastics Regulation (recommendation 8.2), to develop a single, national framework for improving the efficiency and effectiveness of agricultural and veterinary chemicals regulation for its consideration in the first half of 2010. National competency requirements for the aerial application of agricultural chemicals are being considered as part of the PIMC/COAG process.

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Question: APVMA 09

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Research Permits
Hansard Page: Written

Senator Abetz asked:

Is it APVMA's view that the public should be notified:

(a) when research permits for agvet chemicals are granted:

(b) of the chemicals involved in those permits; and

(c) the locations and dates on which those permits may operate.

What are the reasons for APVMA's view?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a statutory agency that operates in accordance with its enabling legislation. This includes the Agvet Code that is scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The Agvet Code requires the APVMA to maintain a Record of Permits, which is kept in two parts. All information about research permits issued by the APVMA is currently kept in the confidential part of the Record of Permits.

The Agvet Code specifically prohibits disclosure of confidential commercial information (CCI) by the APVMA. It is the APVMA's view that it is not able to lawfully disclose the chemicals involved in a research permit or the locations and dates of any research under the permit as that information is CCI.

The APVMA will be reviewing whether all information about research permits should be treated as CCI for the purposes of the Agvet Codes. The purpose of the review will be to identify the extent of the information that the APVMA could make publicly available via the Record of Permits without jeopardising the confidentiality of material that is genuinely confidential. The APVMA will consult with stakeholders to inform its review.

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Question: APVMA 10

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: COAG's Regulatory Reform Agenda
Hansard Page: Written

Senator Back asked:

1. What measures have been taken at APVMA to streamline operations at APVMA in accordance with their commitment to work on "*COAG's regulatory reform agenda"*?
2. Has APVMA taken an additional staff and can it confirm which areas are they working in?
3. Has APVMA accepted staff cut from other divisions?

Answer:

1. In 2007 the Australian Pesticides and Veterinary Medicines Authority (APVMA) implemented a new organisational structure to enable it to achieve its objectives more effectively and efficiently under new governance arrangements that commenced in July 2007. The new organisation structure also streamlined APVMA operations with respect to its regulatory reform work. Staff resources freed up as a result of the structural reform were used to establish a new Reform Manager position responsible for regulatory reform work. This year the APVMA has increased resources allocated to regulatory reform work to the equivalent of 2.5 full-time equivalent staff.
2. Two full-time and one half-time staff are currently engaged to assist with the reform agenda, including COAG's regulatory reform agenda.
3. The APVMA is an independent agency. APVMA has not had staff cuts in any of its programs or divisions during the last two years.

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Question: APVMA 11

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Cost Recovery Review
Hansard Page: Written

Senator Back asked:

APVMA has undertaken a cost recovery review:

1. Is this completed and if not, when is it expected to be completed and what is the cause of the delay?
2. Can you provide of the names of the individuals and positions responsible for this review?
3. Has its cost been factored into the budget?
4. What are the implementation costs?
5. What impact will the extension of the implementation time frame have on the budget for the review?

Answer:

1. The cost recovery review is nearing completion.

2. The Program Manger Corporate Services is the executive officer responsible for the review. A number of other senior APVMA staff have been involved with the review.

3 The cost of the review was spread across the 2008-2009 and 2009-2010 financial years and was included in the budget for both years.

4. Implementation will be undertaken within current resources.

5. The additional time taken to finalise the review will not increase the budget for the review.

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Question: APVMA 12

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Registration Applications
Hansard Page: Written

Senator Back asked:

APVMA has indicated that it is experiencing high volumes of work stating at last estimates that "at any one time it 2,500 registration applications before it and about the same were finalised every year and 700 or so permit applications of which 700 – 800 are finalised each year."

1. Can you provide me with accurate information on the number of registrations and permits applications received and processed each year?
2. Have you made any progress with the addition of extra staff members and the implementation of regulatory reforms?
3. If not, why?

Answer:

1. In the tables below are presented the performance statistics requested for product and permit applications. These statistics are published in the Australian Pesticides and Veterinary Medicines Authority (APVMA) Annual Report and are reported quarterly on the APVMA website at the following link: http://www.apvma.gov.au/perfreporting/subpage_reporting.shtml

Product Applications (2004 to 2009)

Financial Year	Product Applications Received	Product Applications Finalised
2008/2009	2494	2257
2007/2008	2381	2260
2006/2007	2439	2279
2005/2006	2202	2260
2004/2005	2377	2300

Question: APVMA 12 (continued)

Permit Applications (2004 to 2009)

Financial Year	Permit Applications Received	Permit Applications Finalised
2008/2009	672	680
2007/2008	788	738
2006/2007	700	634
2005/2006	746	862
2004/2005	971	878

2. A restructure in 2007/2008 led to staff changes in the registration sections with additional staff being recruited to handle less complex registration applications. These staff members are starting to reach their full potential following training and learning of registration processes. Performance statistics at the end of this financial year should better reflect staff training and process improvements.

   Six new staff in the chemistry section have worked hard over the past 12 months to remove the backlog of applications in that area. In addition, the ability to receive fully electronic applications has improved the processing and completion times for some product types. Further regulatory reforms in the registration process are currently under consultation with industry.

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Agriculture, Fisheries and Forestry

Question: APVMA 13

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Commercial in Confidence Information
Hansard Page: Written

Senator Back asked:

It has been reported in the Business Spectator that APVMA is "dysfunctional" and revealed that on two occasions APVMA has disclosed confidential commercial information about product formulations to competitors.
APVMA only advised the victim by letter of APVMA's error in August 2008 that these incidents had occurred in March and April 2007.

1. Why did APVMA decide to take no action until over a year later?
2. Was a review conducted into how this had occurred?
3. What action has been undertaken to address this negligence?
4. Is there any substance to the allegation that a bullying letter was sent to competitor's registration consultant threatening a jail term of up to two years if the consultant disclosed the confidential information to anyone else?
5. APVMA's governing legislation provides for up to two years jail for disclosing confidential information. Why was a company who was only privy to this information, due to apparent negligence on APVMA's part threatened with jail?
6. If the person responsible within APVMA is / has been identified, is imprisonment being considered?
7. Have there been other cases of disclosure of product formulation information by APMVA? Or any administrative blunders?

Answer:

1. The APVMA acted quickly once it became aware that confidential commercial information may have been disclosed. When the first disclosure was detected the APVMA implemented an audit of all files that had been handled by the particular product evaluator in question and an audit of 600 files that had been handled by other product evaluators.

   The APVMA followed its standard process when a disclosure of confidential commercial information is detected. This is to firstly contact the recipient of the information and seek to extract an undertaking from them that they will either return the information to the APVMA or destroy it and that they will not use it, or seek to benefit from it, in any way. The Agvet Code does not give the

Question: APVMA 13 (continued)

APVMA any powers of compulsion in this area and the APVMA has to rely on the goodwill of the recipient to give the undertaking. This process took some months with one of the undertakings not being given to the APVMA until February 2009.

2. Yes.

3. The APVMA has undertaken several actions to address the disclosures. A directive was issued immediately to all staff that all outgoing correspondence in the product evaluation areas that might potentially contain confidential commercial information be checked by an ongoing employee at the EL1 classification or above prior to the letter being sent. The APVMA revised and finalised its internal guidelines for evaluators on confidential commercial information, held staff briefings and training sessions and is currently finalising an on-line training tool on how to handle confidential commercial information. The APVMA also conducted a follow-up CCI audit in May 2009 which revealed that there were no further disclosures of CCI since the issuing of the directive. The directive remains in place as a reminder to all staff about the processes that must be followed in relation to correspondence containing CCI information.

4. No.

5. The letter set out the legislative obligations of s.162(6) of the Agvet Code.

6. No.

7. Yes. The audit showed that the product evaluator in question had inadvertently made two other disclosures of product formulation information.

Senate Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2009

Agriculture, Fisheries and Forestry

Question: APVMA 14

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Imtrade
Hansard Page: Written question

Senator Back asked:

Further accusations of dysfunction have been levelled at the APVMA who has settled and will pay legal costs with Imtrade a WA crop chemical company who claimed that APVMA had unlawfully deregistered their products.

1. To date has APVMA been successful in increasing their fees to cover the cost of the settlement and payment of legal costs to Imtrade?
2. What does this equate to?
3. Has there been an increase in services fees and of how much?
4. Can you provide me with a breakdown?
5. Will this increase be added to the final costs outlined in the forthcoming cost recovery review?
6. Finally, how does APVMA respond to concerns that this is causing a high level of dissatisfaction and now reluctance by business in registering their products or dealing with it?
7. What is APVMA doing to safeguard its reputation or even better, restore confidence?
8. Has the Minister been briefing or advised of the increasing reports of dysfunction and administrative blunders within his own Department at APVMA?
9. What action has been taken to restore confidence the agricultural chemical industry's confidence in the national regulator?

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has not sought to increase its fees in any way to cover the cost of the settlement with Imtrade and the payment of Imtrade's legal costs.

2. Not applicable.

3. Not applicable.

4. Not applicable.

5. Not applicable.

6. The APVMA is not aware of any high level of dissatisfaction or reluctance by business to register their products or deal with the APVMA.

Question: APVMA 14 (continued)

7. The APVMA's Corporate Plan notes this will be achieved through:
   - promoting confidence through consistent, predictable and transparent decision-making.
   - enhancing awareness of how our regulatory activities protect people, the environment and trade.
   - engaging with other government agencies to enhance regulatory efficiency.
   - enhancing the capability of our people and our systems.

8. The APVMA informed the Minister's Office after initial comments were made in a blog on an on-line publication. The APVMA has monitored subsequent postings.

9. The APVMA is aware that there were concerns from industry about registration performance during 2009. Registration assessment timeframe performance dropped largely because of staffing issues in the chemistry area. This created a backlog in the assessment of product applications. The APVMA put strategies in place to address the backlog and informed industry that it expected the backlog to be eliminated and registration assessments to be back on timeframe by late October 2009. The APVMA achieved this in early September 2009. At the Industry Liaison Committee meeting on 5 November 2009, representatives of industry complimented the APVMA on its efforts and performance in getting the chemistry assessments back within timeframe.

Senate Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2009

Agriculture, Fisheries and Forestry

Question: APVMA 15

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Endosulfan
Hansard Page: Written

Senator Colbeck asked:

1. Can the APVMA give an update regarding the status of endosulfan?
2. What is the volume of endosulfan used for agricultural purposes in Australia?
3. What are the major industries to use endosulfan in Australia?
4. Can the APVMA provide a breakdown by industry?
5. Do you have any statistics on use in Tasmania?
6. Can the APVMA provide a breakdown by State/Territory?
7. What is the process with which the APVMA would bring about a deregistration of endosulfan?
8. What consultation processes are required?
9. What are the timeframes for a deregistration?

Answer:

1. Currently there is no change to the registration status of endosulfan in Australia.

2. The Australian Pesticides and Veterinary Medicines Authority (APVMA) does not collect usage data.

3. The APVMA understands that the major industries using endosulfan are limited to some tropical fruits, citrus and tree nuts. There is very little broadacre use of endosulfan, especially in cotton due to the planting of genetically modified cotton varieties. In all industries, sprays are limited to one or two per season as an insect resistance management practice.

4. Refer to answer to question 2.

5. Refer to answer to question 2.

6. Refer to answer to question 2.

7. Endosulfan could be deregistered as the result of a reconsideration under the APVMA's chemical review program. Endosulfan is not currently the subject of a review.

Question: APVMA 15 (continued)

8. The normal consultation processes with the APVMA's advising agencies (the Office of Chemical Safety and Environmental Health in the Department of Health Aging; the Chemical Assessment Section in the Department of the Environment, Water, Heritage and the Arts), the states and territories as

   National Registration Scheme partners, Food Standards Australian New Zealand, the relevant chemical manufacturers and registrants, and the general community would be undertaken as part of any APVMA review.

9. The timeframes for deregistration could be as short as a few months. The timeframe will depend on time taken by Commonwealth and state and territory agencies to provide advice. The APVMA would undertake a short public consultation period before making its decision.

Senate Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2009

Agriculture, Fisheries and Forestry

Question: APVMA 16

Division/Agency: Australian Pesticides and Veterinary Medicines Authority
Topic: Cost Recovery Review
Hansard Page: Written

Senator Colbeck asked:

1. What is the status of the Final Cost Recovery Impact Statement, and the introduction of the new arrangements?
2. What is the reason for the extended review period and what impact will this have on APVMA's budget?
3. What will the delay mean in terms of fee increases?
4. Will applicants be paying higher fees once the new arrangements begin, to offset the presumed lesser fees paid by applicants during July 1 2009 and June 30 2010??

Answer:

1. The cost recovery review is nearing completion.

2. The extended review period allowed Australian Pesticides and Veterinary Medicines Authority (APVMA) to consult more widely. The APVMA will operate according to its current budget until any new arrangements are agreed and regulated. The budget for 2009-2010 assumes implementation of the new fees in December 2009. A delay beyond December 2009 will mean that the APVMA will carry a budget deficit for 2009-2010.

3 At least three months notice will be given of application fee increases. If agreed, annual fee increases will take effect on 1 July 2010.

5. There will be no increase in fees to off set any implementation delay.