Chapter 3

Issues

Overview

3.1 Witnesses generally supported reform of the current system for the approval and registration and review of agricultural chemicals and veterinary medicines (agvet) chemicals. The Queensland Department of Agriculture, Fisheries and Forestry for example, submitted that it supports a number of the bill's provisions, including the introduction of a periodic review of a chemical's safety through a re-registration and re-approval scheme.[1] Mr Michael Tichon, an agvet chemicals registration consultant, although having reservations concerning some provisions of the bill, submitted that the bill contains many improvements.[2]

3.2 While there was general support for reform of the agvet chemicals registration process, a number of witnesses considered that the changes proposed in the bill would not achieve the government's aims.

3.3 The WFF and the National Toxics Network (NTN), for example, submitted in a joint submission that they were not confident that there would be sufficient improvement to the protection of human health and the environment as a result of the proposed reforms.[3] The organisations submitted that the bill should be strengthened to oblige the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ban − and ban quickly − the most dangerous pesticides used in Australia, the ones that are already banned overseas.[4] Similarly, the Alliance for a Clean Environment submitted that:

> The current regulatory model is focussed on pre market assessments and registration which support industry getting their products onto the market as quickly as possible. This is not a framework that is balanced with the protection of human health and the environment despite being stated in the Bill.[5]

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1 Queensland Department of Agriculture, Fisheries and Forestry, *Submission 11*, p. 2.

2 Mr Michael Tichon, *Submission 20*, p. 1.

3 WWF-Australia and the National Toxics Network, *Submission* 25, p. 1.

4 Mr Nick Heath, WWF-Australia, *Committee Hansard*, 4 February 2013, p. 1.

5 Alliance for a Clean Environment, *Submission 26*, p. 2.

3.4 A registered chemical user organisation, the Australian Forest Products Association (AFPA), submitted that the bill seems to have fallen well short of the stated objective to improve the efficiency and effectiveness of the current regulatory arrangements and to provide greater certainty.[6] Mr Matthew, representing the Association, considered that the bill would appear to increase the amount of red tape, and process and cost recovery fees with little in the way of increased efficiencies or certainties.[7]

3.5 An organisation representing registrants, manufacturers and formulators of animal health products, the Animal Health Alliance (AHA), stated that:

> This latest attempt by government to deal with APVMA inefficiencies through the Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012, does not, in the Alliance's opinion, do anything to address the fundamental problem. In fact this new Bill actually increases the regulatory burden on industry and imposes more work for the APVMA without any demonstrable cost/risk benefit to warrant such a move.[8]

3.6 Concerns that were raised in the evidence about specific provisions contained in the bill are discussed in this Chapter. Among them are the provisions for re-registration and re-consideration; the risk-based registration process; minor use; costs; and enforcement.

Re-registration and re-approval

3.7 The Government stated in the Explanatory Memorandum that Australia does not have a requirement for regular review, and that the bill provides for a mandatory scheme for re-approval and re-registration.[9] In the Regulatory Impact Statement (RIS), the Government refers to:

> …the possibility that some agvet chemicals that present an unacceptable risk to the Australian community and/or environment remain on the market without appropriate risk management measures in place.[10]

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6 Australian Forest Products Association, *Submission 12*, p. 4.

7 Mr Gavin Matthew, Australian Forest Products Association, *Committee Hansard*, 4 February 2013, p. 22.

8 Animal Health Alliance (Australia) Ltd, *Submission 6*, p. 1.

9 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, p. 3.

10 Better Regulation of Agricultural and Veterinary Chemicals, Regulation Impact Statement, November 2011, p. 11, http://ris.finance.gov.au/files/2011/11/04-Better-Regulation-of-AGVET.pdf (accessed 25 January 2013).

3.8 Re-registration is a feature of a number of registration schemes in like countries overseas. The WFF-NTN submitted that the Government had made an election commitment in 2007 to a re-registration scheme, and that 'this will help to bring Australia into line with other comparable jurisdictions such as the USA and the EU that have registrations schemes…'[11]

3.9 The APVMA now conducts chemical reviews on an ad hoc basis when interested parties, including industry or the APVMA itself, identify potential problems.[12]

3.10 The RIS sets out in some detail how it is proposed that chemical reviews should be processed in a three-tier process.[13]

3.11 The first tier would cover all currently registered products and would entail those holding approvals or registrations (registrants) answering a number of set questions. In the Government's view, registrants could reasonably be expected to be in possession of the information sought and so there should not be a requirement for registrants to produce additional data. A Department of Agriculture, Fisheries and Forestry (DAFF) witness, Mr Kelly, informed the committee that if the product is in the market and there are no reasonable grounds to doubt that the product is safe, then the product should be re-registered.[14]

3.12 If there are doubts raised at the first part of the process the product would proceed to the second tier. According to the RIS, 'the tier 2 assessment would determine whether the issues about the product identified in tier 1 were worthy of further investigation, and what kind of investigation should take place.'[15] At this stage:

> The tier 2 process would determine whether it is necessary to request further information from the registrant and what that information should be. At tier 2, the APVMA may seek information from overseas regulators about

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11 WWF-Australia and the National Toxics Network, *Submission 25*, p. 2.

12 The current Code Act [s.161] requires that registrants and approval holders, if they become aware of 'any relevant information in relation to the constituent or in relation to [a] product or of any of its constituents' must provide that information to the APVMA.

13 Better Regulation of Agricultural and Veterinary Chemicals, Regulation Impact Statement, November 2011, p. 22, http://ris.finance.gov.au/files/2011/11/04-Better-Regulation-of-AGVET.pdf (accessed 25 January 2013).

14 Mr Marc Kelly, Department of Agriculture, Fisheries and Forestry, *Committee Hansard*, 4 February 2013, p. 55.

15 Better Regulation of Agricultural and Veterinary Chemicals, Regulation Impact Statement, November 2011, p. 22.

> their registration decisions or seek advice from regulatory partners on component assessments or particular issues…[16]

Registrants would be requested to provide a submission at this stage.

3.13 Following the tier 2 review a chemical might be approved with conditions; rejected with the registrant having the opportunity to apply anew for registration or approval; or referred for tier 3 review.

3.14 Another submission based on the results of the tier 2 review would be requested at this third stage. Once again, re-registration might be granted subject to conditions or rejected, with the registrant having the opportunity to apply anew for registration or approval.

3.15 Importantly, if the registrant were to fail to provide information at any of the three stages in accordance with an APVMA request, the Authority would be able to suspend or cancel the registration.[17]

3.16 Support for a scheme of mandatory reviews came from the WWF-NTN which submitted that:

> The fact remains the APVMA has a backlog of old chemistries (which make up the bulk of the pesticide inventory in Australia) to review. These chemistries were 'grandfathered' into the national scheme without ever having full health and environment risk assessments.
>
> Comparable jurisdictions have since banned some of the chemistries still widely used in Australia, because they did not meet contemporary health and environmental standards.[18]

3.17 The witnesses tabled a document listing pesticides that were of concern to them, 80 of which had been 'banned' in the European Union (EU) but were still available in Australia.[19] Subsequently, 12 of the pesticides on the list have been registered for specific uses in parts of the EU.[20]

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16 Better Regulation of Agricultural and Veterinary Chemicals, Regulation Impact Statement, November 2011, p. 22.

17 Better Regulation of Agricultural and Veterinary Chemicals, Regulation Impact Statement, November 2011, p. 22.

18 WWF-Australia and the National Toxics Network, *Submission 25*, p. 1.

19 Jo Immig, Coordinator, National Toxics Network, *A list of Australia's most dangerous pesticides*, WWF-NTN, July 2010.

20 National Toxics Network, answer to question on notice, (received 12 February 2013).

3.18 Some other witnesses, however, do not agree that the proposed re-registration processes are needed. In CropLife's view, for example, 'the new processes do not address any regulatory gap',[21] and the AHA submitted that:

> The Alliance has not sighted…any demonstrated evidence of market failure with veterinary chemical products compliance programs that would support the argument for a tiered reapplication, review and re-registration scheme. As such, the Alliance cannot support this proposed scheme.[22]

3.19 Similarly, the NSW Farmers Association submitted that it was:

> …concerned that the proposed review system may redirect resources and efforts away from high risk chemicals or products to those with a low risk. It is believed that the chemical review process is best managed through a targeted risk-based review program, which is currently provided through the existing chemical review program.[23]

Off-patent products

3.20 There were also concerns that the proposed chemical review process would result in older, useful and cheaper chemicals being withdrawn from the market. The Veterinary Manufacturers and Distributors Association (VMDA) submitted that mandatory reconsideration has the potential to deprive veterinarians, farmers and animal owners of proven products. The VMDA considers that review should focus on veterinary products with reported adverse effects and that the proposed arrangements are 'an invitation to anybody including special interest groups to "swamp" the APVMA with potentially frivolous demands for reconsideration, which will have to be considered utilizing valuable and scarce resources'.[24]

3.21 The Victorian Government Minister for Agriculture and Food Security submitted that:

> A possible outcome of the proposed arrangements is that current agricultural and veterinary chemicals could be lost, which could impact adversely on Australian and Victorian farmers' ability to produce

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21 CropLife Australia Limited, *Submission* 16, p. 4

22 Animal Health Alliance (Australia) Ltd, *Submission 6*, p. 7.

23 NSW Farmers' Association, *Submission 33*, Attachment C, p. 7.

24 Veterinary Manufacturers and Distributors Association, *Submission 24*, p. 4.

> commodities for domestic and export trade. This in turn could adversely affect Australia's and Victoria's economies.[25]

3.22 The AHA also considered that mandatory review could result in the withdrawal of low-cost generic products from the market:

> The proposed targeted reapplication, review and re-registration scheme would be working in a commercial environment where the Australian market is dominated by generic agvet chemical products. The incentive for such registrants to allocate resources, let alone generate contemporary data for their existing products is problematic.[26]

3.23 The Australian Veterinary Association referred to an agvet chemical, *permethrin*, which is used as an insecticide compound, that was off-patent and generally available that was lost from the registration compendium in the EU because no-one would put up money for the extra requirements for its re-registration. It was replaced with medications that had a lesser safety record.[27]

3.24 Some witnesses also considered that those registrants who successfully sought re-registration would incur additional costs which would be passed on to farmers.[28]

3.25 When asked why there was a perception in the industry and among chemical users that the review processes would result in the loss of many generic products from the Australian market, DAFF responded:

> I think that the difficulty comes because the re-registration scheme proposed in the bill is so different to that overseas. This system was designed with the characteristics of the Australian market in mind. We know we are a small market and that an additional cost impost on a chemical company might result in them withdrawing their product from the market. So we need to limit that impost. Unlike overseas, we do not require that gaps in data—the dossier in the file for registered products—be filled up. We do not require that they produce new data to support the product in the market.[29]

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25 Mr Peter Walsh MLA, Minister for Agriculture and Food Security, *Submission 39*, p. 2.

26 Animal Health Alliance (Australia) Ltd, *Submission 6*, p. 11.

27 Dr Bruce Twentyman, Australian Veterinary Association *Committee Hansard*, 4 February 2013, p. 33.

28 See, for example, Mr Matthew Cossey, *Committee Hansard*, 4 February 2013, p. 37.

29 Mr Marc Kelly, DAFF, *Committee Hansard*, 4 February 2013, p. 55.

3.26 DAFF informed the committee that it was proposed to charge $700 for a re-registration application which would last between 7 and 15 years and that 'chemical industry representatives…do not see the cost of a re-registration fee as overly onerous'.[30] This cost is for the first step in the proposed three-tier process. In the words of a departmental witness, if there is 'the sniff of a doubt'[31] at the first stage, the product would progress to the second tier of the re-registration process. This stage would require the generation of potentially expensive data and may well cause manufacturers to consider whether to continue to seek re-registration.

Committee view

3.27 The committee considers that mandatory review of agvet chemicals should ensure that assessments of all registered and approved products will occur on a regular basis so that they remain up-to-date. The committee is mindful that the proposed chemical reviews would implement an election commitment of the Government which is intended 'to ensure the ongoing safety of agricultural chemicals and veterinary medicines and improve the current chemical review arrangements'.[32]

3.28 It notes, however, that a number of submitters suggested that manufacturers of low-value but widely used chemicals, owing to the additional costs of the scheme, might not seek to renew registration of useful and widely-used chemicals. In the case of generic products no-one might be prepared to accept the responsibility and associated cost of seeking re-registration. If this were to happen, it would limit the availability of a range of agvet chemicals to industry and users.

3.29 In considering these possibilities the committee notes that the operation of the proposed system will be subjected to a mandatory review after five years of operation. It assumes that, if the deleterious effects predicted by some witnesses become evident, the Government would take corrective action that might include making appropriate legislative changes.

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30 Mr Marc Kelly, DAFF, *Committee Hansard*, 4 February 2013, p. 55.

31 Mr Marc Kelly, DAFF, *Committee Hansard*, 4 February 2013, p. 65.

32 Mr Sid Sidebottom MP, Parliamentary Secretary for Agriculture, Fisheries and Forestry, Second Reading Speech, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, House of Representatives, *House of Representatives Hansard*, 28 November 2012, pp 13658–13660, http://parlinfo.aph.gov.au/parlInfo/genpdf/chamber/hansardr/50ef4858-02bd-437b-a64f-599769ecfec6/0029/hansard_frag.pdf;fileType=application%2Fpdf (accessed 20 February 2013).

Risk analysis

3.30 The Government stated in the Explanatory Memorandum that:

> …the Agvet Code is to be implemented through science-based risk analysis, including risk assessment and management… Risk analysis provides a scientific, structured, systematic and transparent method for making decisions. It allows the risks of agvet chemicals to be considered on the basis of relevant, reliable and sound scientific evidence within the overall context of human and animal health and safety and environmental protection.[33]

3.31 A number of submitters, however, urged that the assessment of agvet chemicals should be based on 'the precautionary principle', which was usefully defined in the submission made by Save Our Trees:

> Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public bears the burden of proof.[34]

3.32 The Alliance for a Clean Environment stated that:

> To bring this regulatory model towards balancing the needs of industry (who in fact are part of the community) with the rights of our citizens enshrined under international treaties and conventions (which Australia is a signatory) for a safe and clean environment in which to live, a greater focus is needed to uphold risk management, monitor residues and health impacts and provide for lower risk and less hazardous chemicals underpinned by the precautionary principle.[35]

3.33 CropLife commented on the application of the precautionary principle to the assessment of agvet chemicals:

> …proponents of the Precautionary Principle in regulatory decision making often misconstrue its content, ignoring economic elements that form part of most constructions, including that expressed at the 1992 Rio World Summit. CropLife does not support the Precautionary Principle as a sound basis for regulatory decision making on the basis that its content is

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33 Explanatory Memorandum, p. 19.

34 Save Our Trees, *Submission 14*, p.1.

35 Alliance for a Clean Environment, *Submission 26*, p. 2.

> uncertain and it is often incorrectly called upon to support regulatory action that is not justified by a proper understanding of the genuine risk presented by any particular product.[36]

Unmanageable risk

3.34 Paragraph 1A(2)(d) of the bill states that the Agvet Code is to be implemented in a manner that recognises that the use of chemical products that pose unmanageable risks to the health and safety of human beings, animals and the environment is not appropriate in Australia.

3.35 Some witnesses expressed concern that the term 'unmanageable risk' is not defined. The joint submission made by WWF-Australia and the NTN submitted that:

> If the Code is to be implemented with the intention that unmanageable chemicals and products are not appropriate, it's critical a definition of 'unmanageable risk' is explicit in the Bill, along with clauses spelling out how it will be operationalised in a transparent and accountable manner, giving certainty to the public and industry.[37]

3.36 Mr Heath representing the WWF informed the committee that the organisation was concerned that there was no head of power in the bill that would oblige the APVMA to act on those chemicals in a certain time. He stated that, even if the APVMA acted on a particular chemical, the assessment could be strung out to 11.5 years.[38] The organisations' submission states that there's no point wasting regulatory resources on chemistries, which by definition, present 'unmanageable risk' based on their inherent toxicological hazards and the risk of exposure to them. By keeping these products on the market the regulator is blocking the way for newer, safer products to get to market.[39]

3.37 Ms Immig of the NTN stated that unmanageable pesticides should be removed immediately from the market if there are viable and safer alternatives, but that there should be an upper limit of no more than three to five years to get these sorts of products off the market.[40]

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36 CropLife Australia, *Submission 16*, Attachment C, p. 11.

37 WWF-Australia and National Toxic Network, *Submission 25*, p. 3.

38 Mr Nick Heath, *Committee Transcript*, 4 February 2013, p. 2.

39 WWF-Australia and National Toxic Network, *Submission 25*, p. 3.

40 Ms Joana Immig, *Committee Hansard*, 4 February 2013, p.3.

3.38 Although the AHA's interest is in veterinary medicines rather than pesticides, the Alliance's Chief Executive Officer remarked that

> We must not lose sight of the fact that we have a regulator which has a legislated remit to manage risk. Either they can be satisfied on the risk or they cannot. The debate about unacceptable risk actually confuses the issue. The regulator is either satisfied on the risk to register a product or to amend the particulars of that registered product or they are not.[41]

Risk Compendium

3.39 The Government has stated that the quality of applications for approvals, registrations and reconsiderations will be enhanced by the development, publication and implementation of a risk framework. The framework, or Risk Compendium, which is to describe the policies and processes the APVMA will use to assess and manage risk across its regulatory activities, is integral to the operation of the new scheme.[42]

3.40 The APVMA has published the first of two volumes that will comprise the Compendium. Volume 1 includes a series of framework documents describing the principles that will guide the APVMA's regulatory decisions and activities. The second volume will contain more detailed process documents describing how the APVMA will carry out its regulatory functions but this will not be completed until 2014, after the time proposed for the enactment of the legislation.[43]

3.41 The APVMA has stated that the objective of the Compendium is to make chemical assessment and reconsideration (chemical review) more predictable, and to better describe how its assessment effort is aligned with risk. According to the Authority the Compendium will be built and released over time as it works with its stakeholders to develop systems and processes to implement the new regulatory framework. The Compendium will aid understanding of the APVMA's regulatory processes, requirements and decision-making.[44]

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41 Dr Peter Holdsworth, *Committee Hansard*, 4 February 2013, p. 14.

42 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, p. 1.

43 *Better regulation of agricultural and veterinary chemicals*, Australian Government, Australian Pesticides and Veterinary Medicines Authority, www.apvma.gov.au/about/work/better_regulation/index.php (accessed 31 January 2013).

44 *Better regulation of agricultural and veterinary chemicals*, Australian Government, Australian Pesticides and Veterinary Medicines Authority.

3.42 Some witnesses were concerned about the timing and the content of the Risk Compendium. Mr Matthew of the AFPA stated that there is continued uncertainty in the detail and the application by the regulator of the proposed risk assessment framework.[45] Mr Cossey of CropLife Australia stated that the proposed commencement dates do not allow sufficient time for the development of essential risk frameworks and associated operational documentation by the regulator.[46] A registration consultant, Mr Tichon, informed the committee that:

> …I am afraid the guidelines that the APVMA has issued so far in the risk compendium do not adequately articulate what is required for…new technologies. In fact it is very difficult for them to do that because at the time any document is prepared you do not know what is around the corner in terms of new technologies. What is really needed is ongoing dialogue between people developing these technologies and the regulator.[47]

Committee view

3.43 The committee considers that the risk-based processes proposed in the bill are appropriate for the assessment, approval and registration of agvet chemicals. The bill makes clear that the amended Agvet Code is to be implemented in a manner that balances regulatory effort (and regulatory burden) with the level of chemical risk to the health and safety of human beings, animals and the environment.[48] The committee believes that adopting a risk-based approach will provide a sensible and effective allocation of the APVMA's necessarily limited resources.

Regulatory costs

3.44 The Government has acknowledged that the re-registration and re-approval process will introduce additional costs to approval holders and registrants who under the existing system are not subject to re-registration. It considers, however, that these additional costs would be outweighed by the benefits to the broader community through improvements to the chemical review program and greater confidence in the integrity of the National Registration Scheme.[49]

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45 Mr Gavin Matthew, *Committee Hansard*, 4 February 2013, p. 22.

46 Mr Matthew Cossey, *Committee Hansard*, 4 February 2013, p. 36.

47 Mr Michael Tichon, *Committee Hansard*, 4 February 2013, p. 18.

48 Agricultural and Veterinary Chemicals Legislation Bill 2012, proposed section 1A.

49 *Better regulation of agricultural and veterinary chemicals*, Australian Government, Australian Pesticides and Veterinary Medicines Authority, Conclusions, p. 46.

3.45 Most evidence received by the committee indicated the new processes would result in significantly increased costs to the Australian agvet industry. ACCORD Australasia, for example, which represents manufacturers and suppliers of formulated (chemical) products submitted that:

> It has been estimated that these reforms will significantly increase the cost to agricultural chemical producers by as much as 30% each year. In turn, this increase in cost recovery from the industry may have a detrimental effect on the availability of accessible chemicals for Australian production systems. It is therefore essential that industry is a beneficiary of the reform process - the cost increases in the quantum identified are simply not sustainable.[50]

3.46 The 30 per cent figure (approximately $8 million per annum) was obtained from a 2010 APVMA cost recovery discussion paper which was analysed for CropLife in February 2012 by Deloitte Access Economics.[51] More recently, in November 2012 APVMA published a Cost Recovery Impact Statement that estimated the additional cost of re-registration and re-approval at approximately $2 million per annum from 2015-16, by which time the new processes are to be scaled up.[52] That figure does not include an estimated additional annual cost of $814 289 for the increased compliance and enforcement activities proposed in the bill.[53]

3.47 DAFF informed the committee that the estimated 30 per cent increase had been based on the original 2010 proposals for the re-registration scheme but that the scheme had since been refined to take costs out of the system. Additionally, the APVMA's cost recovery impact statement had not then been updated.[54]

3.48 Although the costs to industry may be not of the order suggested by some witnesses, an additional impost nevertheless remains. A concern expressed by a number of witnesses was that a quantitative cost benefit analysis had not been done to justify the proposed scheme. Mr McKeon of the National Farmers' Federation (NFF) stated that:

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50 ACCORD Australasia, *Submission 17*, p. 2.

51 Deloitte Access Economics, Review of APVMA Cost Recovery Discussion Paper prepared for CropLife Australia, 16 February 2012, p. 2, *Submission 16*.

52 Australian Government, Australian Pesticide and Veterinary Medicines Authority, *Cost Recovery Impact Statement covering the period 1 July 2013-30 June 2015*, p. 26.

53 Australian Government, Australian Pesticide and Veterinary Medicines Authority, *Cost Recovery Impact Statement covering the period 1 July 2013-30 June 2015*, p. 22.

54 Mr Thomas Parnell, Department of Agriculture, Fisheries and Forestry, *Committee Hansard*, 4 February 2013, p. 54.

> We would fully support [the proposed scheme] being exposed to a clear, full cost-benefit analysis undertaken before the application or the introduction of a registration process, to actually look at what each of the issues are, what some of those opportunity costs are that the industry may miss out on from having products removed from the market and what the real costs would be of implementing a scheme such as reregistration.[55]

3.49 A DAFF witness stated that the Government had not done a quantitative cost-benefit analysis, but that the Government had been through a Productivity Commission inquiry and an Australian National Audit Office (ANAO) report and had produced a RIS. The Government had concluded that the benefit of reforming the system was greater than the cost.[56] In the Explanatory Memorandum the Government stated that business would benefit through increased certainty over regulatory requirements and timeliness, reduced application requirements where permitted by appropriate risk management, improved data protection provisions and increased community confidence in regulatory outcomes.[57]

3.50 DAFF is currently undertaking a 'first principles' review of the cost of the APVMA and how those costs should be apportioned and who should pay for them.[58] Some witnesses drew attention to costing regimes in similar countries overseas where some costs are met by government. In relation to the costs of compliance and enforcement, a DAFF witness commented that there was an element of a community good in compliance, but also an element of private good.[59]

Committee view

3.51 The bill would require industry to fund additional re-registration and re-approval processes and to pay additional compliance costs. The quantum of these

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55 Mr David McKeon, National Farmers Federation, *Committee Hansard*, 4 February 2013, p. 51.

56 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, *Committee Hansard*, 4 February 2013, p. 59.

57 Explanatory Memorandum, p. 1.

58 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, *Committee Hansard*, 4 February 2013, p. 64.

59 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, *Committee Hansard*, 4 February 2013, p. 64.

costs is estimated to be approximately $2.8 million annually from the time the scheme is expected to be fully operational in 2015-16.[60]

3.52 Benefits to business are not easy to quantify, but in the view of the Government they would outweigh the costs. The Government also expects that there will be additional benefits from the proposed amendments, including providing greater assurance to the public about the safety of new and existing chemicals.

3.53 Given both the public and private benefits the Government expects to accrue from the passage of this bill, the committee will be interested in the conclusions of the costing exercise begun by the department.

Minor use

3.54 An APVMA Information Sheet states that in horticulture, one of the current difficulties is the lack of registered products for use specifically on minor crops.[61] This issue was raised by a number of witnesses who submitted that the bill in its current form does not include an appropriate framework for dealing with minor use.[62] This is a concern because the costs involved in generating data for a minor use may not be recouped from the market[63] and manufacturers are therefore unlikely to seek to register (or re-register) such chemicals. Minor use industries such as forestry and mushroom growing may not have continued access to effective chemical products.

3.55 According to the APVMA, the lack of access to chemicals is partly alleviated by dealing with minor uses as off-label permits, which are issued for a finite period. Off-label permit approvals are generally restricted to products which are already registered and for which the toxicological and environmental data packages have been assessed.[64]

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60 It should be noted, however, that in a written answer to a question taken on notice, the Department quoted a figure of $2 045 023 for 2014-15, which it identified as the ongoing additional cost of implementing the changes.

61 Australian Pesticides and Veterinary Medicines Authority Information Sheet, *Residues and Minor Crops*, www.apvma.gov.au/residues/docs/residues_and_minor_crops_info.pdf (accessed 14 February 2013).

62 See, for example, Mr Gavin Mathew, Australian Forest Products Association, *Committee Hansard*, 4 February 2013, p. 22.

63 Australian Pesticides and Veterinary Medicines Authority Information Sheet, *Residues and Minor Crops*.

64 Australian Pesticides and Veterinary Medicines Authority Information Sheet, *Residues and Minor Crops*.

3.56 The amendments would allow users to access agvet chemicals for minor use either by way of an approval to vary the conditions of a label (with the consent of the registrant) or the issue of an 'off-label' permit.

3.57 The Australian Mushroom Growers Association are concerned about the indeterminate cost of seeking an approval to vary the conditions of a label compared with the permit system. Mr Seymour, the General Manager of the Association, estimated that it costs the Association at least $100 000 each time it applies for a permit for minor use; this cost includes $60 000 for the generation of data.[65]

3.58 Witnesses were also concerned that in the re-registration process minor uses might disappear from the labels of registered products.[66]

3.59 The department informed the committee that while the bill might assist minor users in relation to the use of data, it is not intended to address that issue. Mr Koval stated that:

> Many people are looking at the American system, which has a relatively high cost to it for government… We are looking at ways we provide funds to APVMA already around minor use; we have research and development corporations that do some work around minor use; and we are looking at ways we can perhaps better coordinate and prioritise that type of process to generate some efficiencies. By the same token, we are looking at other ways we can incentivise this system as well. It is a body of work that will continue to be developed over time. The regulation bill is not a minor use bill.[67]

Committee view

3.60 The bill is not intended to, nor does it, address issues surrounding the registration of minor use agvet chemicals, except to the extent that the data protection provisions are relevant. The committee has noted the evidence that there may be an element of public good arising from the registration of chemicals that may not be otherwise available for minor uses. If so, it would expect that the 'first principles' cost inquiry currently being undertaken would identify this good and conclude appropriately.

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65 Mr Greg Seymour, Australian Mushroom Growers Association, *Committee Hansard*, 4 February 2013, p. 26.

66 Mr Gavin Matthew, *Committee Hansard*, 4 February 2013, p. 26.

67 Mr Matthew Koval, *Committee Hansard*, 4 February 2013, pp 66–67.

Enforcement

3.61 As mentioned in Chapter 2, the bill has been considered by the Parliament's scrutiny committees under their terms of reference.

3.62 This committee has not sought to repeat their work, nor to comment on their findings in any detail. It notes, however, that both the Senate Standing Committee for the Scrutiny of Bills and the Parliamentary Joint Committee on Human Rights reported some concerns relating to the extent to which some provisions of the bill might trespass on personal rights and liberties or encroach on the right to privacy.

3.63 Both committees have sought responses from the Minister on their concerns.[68]

Assessment of Veterinary Medicines

3.64 The AHA, which represents registrants, manufacturers and formulators of animal health products, considered that there should be a regulator for veterinary chemical products separate from the regulator responsible for agricultural chemical products. The AHA informed the committee that the Agvet bill is dominated by agricultural chemical issues and that the veterinary chemical industry is caught in the slipstream by virtue of Australia only having one federal regulator dealing with the registration of agricultural and veterinary chemicals. AHA stated that, apart from New Zealand, Australia is the only Organisation for Economic Co-operation and Development (OECD) country that has one primary regulator dealing with both agricultural and veterinary chemical products. Dr Holdsworth, the Chief Executive Officer of the AHA, stated:

> The veterinary chemical industry wants [a veterinary chemicals regulator] and is prepared to pay the cost for an efficient and effective separate regulator. There are many examples of such regulators overseas, namely in the United States of America, Canada, the European Union, Japan and on and on it goes.[69]

3.65 Dr Holdsworth also informed the committee that:

> …the APVMA's position at the moment is that internally they believe they do have a separate process for crop chemicals, pesticides, to that for

68 Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No. 1 of 2013*, 6 February 2013, pp 3 and 6. Parliamentary Joint Committee on Human Rights, *First Report of 2013*, February 2013, p. 4.

69 Dr Peter Holdsworth, *Committee Hansard*, 4 February 2013, pp 11–12.

> veterinary chemicals. They have two streams, but it works under the same legislation and the same operating process.[70]

3.66 The AHA also was concerned that their products, already regulated through the manufacturing licensing scheme, which is administered by the APVMA, would be caught up in the re-registration/re-approval scheme to be implemented by the bill. Although the Association has apparently been informed informally that their products should get an easy transition through the preliminary stages by virtue of the fact that they already have these other mechanisms in place, it argued that it should not have to pay twice – once for the manufacturing licensing scheme and again for re-registration.[71]

3.67 In answer to a question from the committee on the desirability of having separate regulators, Mr Kidd of the NSW Farmers Association responded that Australia has a small population and market and that 'if you had two regulatory authorities, with one struggling at the moment with funding, how would you support funding two?'[72]

3.68 Dr O'Brien, Managing Director of Jurox Pty Ltd, also representing the AHA, informed the committee that his company exports one of its products to Europe and Canada—and will soon be exporting to Japan and America—but that the Europeans will not accept the APVMA regulation and approvals process. The company has to be audited by the Therapeutic Goods Administration (TGA) at a cost of $15 000.[73]

3.69 It is also the case that when veterinarians require single doses of medications that are not otherwise available, these are compounded by pharmacists who must be granted an exemption by the TGA.[74] Additionally, the APVMA sometimes arranges for TGA to conduct audits of manufacturers on the APVMA's behalf.[75]

Committee view

3.70 The committee sees merit in the assessment of veterinary chemicals separate from assessment of pesticides especially because there may be greater equivalence between veterinary medicines and human medicines than between agricultural

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70 Dr Peter Holdsworth, *Committee Hansard*, 4 February 2013, p. 12.

71 Dr Peter Holdsworth, *Committee Hansard*, 4 February 2013, p. 16.

72 Mr Reg Kidd, NSW Farmers Association, *Committee Hansard*, 4 February 2013, p. 49.

73 Dr John O'Brien, *Committee Hansard*, 4 February 2013, p. 13.

74 Dr Bruce Twentyman, *Committee Hansard*, 4 February 2013, p. 30.

75 Mr Neville Matthew, *Committee Hansard*, 4 February 2013, p. 61.

chemicals and veterinary medicines. It also acknowledges that the production of veterinary medicines in Australia is controlled through the manufacturing licensing scheme and that re-approval and re-registration is probably not necessary in this case.

3.71 The bill, however, is not intended to address this matter which may be regarded as a separate matter for further consideration by the Government.

Conclusions

3.72 The committee supports the passage of the bill.

Recommendation 1

3.73 The committee recommends that the Senate pass the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012.

Senator Glenn Sterle

Chair