The Senate

Rural and Regional Affairs and Transport Legislation Committee

Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 [Provisions]

February 2013

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ABBREVIATIONS

AFPA	Australian Forest Products Association
Agvet	Agricultural and veterinary chemicals
AHA	Animal Health Alliance (Australia) Ltd
APVMA	Australian Pesticides and Veterinary Medicines Authority
AVA	Australian Veterinary Association
COAG	Council of Australian Governments
DAFF	Department of Agriculture, Fisheries and Forestry
EU	European Union
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
NTN	National Toxics Network
OECD	Organisation for Economic Co-operation and Development
RIS	Regulatory Impact Statement
VMDA	Veterinary Manufacturers and Distributors Association
WWF	WWF-Australia

LIST OF RECOMMENDATIONS

Recommendation 1

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

Chapter 1
Introduction

Conduct of the inquiry

1.1 The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 was introduced and read a first time in the House of Representatives on Wednesday, 28 November 2012.[1]

1.2 On 29 November 2012, on the recommendation of the Selection of Bills Committee, the provisions of the bill were referred to the Rural and Regional Affairs and Transport Legislation Committee for inquiry and report 27 February 2013.[2]

1.3 The reasons given for the Selection of Bills Committee's recommendation were that there was significant industry and other stakeholder concerns regarding the efficacy of the bill and that an inquiry would allow for further scrutiny of the bill.[3]

1.4 In accordance with its usual practice, the committee advertised the inquiry on its website and in *The Australian*. The committee also wrote to a number of relevant organisations inviting submissions. Thirty-nine submissions were received, as shown in Appendix 1.

1.5 The committee held a public hearing on Monday, 4 February 2013, in Canberra. A list of witnesses who appeared at the public hearing may be found at Appendix 2. The references to the Hansard transcript made in this report are to the proof transcript and page numbers between it and the official transcript may vary. The Hansard transcript of the hearing is available online at the committee's website.

House of Representatives inquiry

1.6 The House of Representatives also referred the bill to its Standing Committee on Agriculture, Resources, Fisheries and Forestry for inquiry. That committee held a public hearing on the same day as the Senate committee and heard from many of the same witnesses. At the time of writing the House of Representatives Committee's report had not been tabled in the House.

Purpose of the bill

1.7 The bill is intended to implement 'reforms to the approval, registration and reconsideration of agricultural and veterinary (agvet) chemicals to improve the efficiency and effectiveness of the current regulatory arrangements and provide

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1 *House of Representatives Votes and Proceedings,* 28 November 2012, p. 2002.

2 *Journals of the Senate*, 29 November 2012, p. 3480.

3 Selection of Bills Committee, *Report No. 16 of 2012*, Appendices 1 and 2.

greater certainty to the community that chemicals approved for use in Australia are safe'.[4] If passed by the Parliament, the following Acts would be amended:

- *Agricultural and Veterinary Chemicals Act 1994*;
- *Agricultural and Veterinary Chemicals Code Act 1994*;
- *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and
- *Agricultural and Veterinary Chemicals (Collection of Levy) Act 1994*.

Structure of report

1.8 The remaining chapters of this report are as follows:

- Chapter 2 describes the background to the bill including the current regulatory environment and the key provisions of the bill; and
- Chapter 3 describes the key issues raised during this inquiry including the provisions for re-registration and re-consideration; the risk-based registration process; minor use; costs; and enforcement.

Acknowledgements

1.9 The committee appreciates the time and effort of all those who provided both written and oral submissions to this inquiry – particularly in view of the short time frame. Their work has assisted the committee considerably in its inquiry.

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

Chapter 2
Background

Current regulatory environment

2.1 Only registered agricultural chemicals and veterinary medicines (agvet chemicals) may be used in Australia. Registration and other aspects of their regulation are administered through a cooperative National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) which was agreed to by the Australian Agriculture Council in 1991.

2.2 The NRS is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities. The assessment and registration of agvet chemicals and the control of supply activities up to the point of retail sale are undertaken on behalf of the states by a Commonwealth Government authority, the Australian Pesticides and Veterinary Medicines Authority (APVMA). Control of use of agvet chemicals after sale is the responsibility of the states and territories.[1]

2.3 The APVMA's operations were described by the Department of Agriculture, Fisheries and Forestry (DAFF) as follows:

> With input from other government agencies, the APVMA approves active constituents and agvet chemical products, undertakes reviews of existing approvals and registrations and monitors the compliance of approvals and registration up to and including the point of retail sale. The APVMA's processes provide assurance, through rigorous science based risk assessments, that agvet chemical use is safe for human and animal health and the environment. They also provide assurance that agvet chemicals will be effective and will not adversely affect Australia's ability to trade agricultural produce. Australia currently has around 9900 separate agvet chemical products registered, each of which contains one or more of around 1883 approved active constituents.[2]

2.4 In addition to approving, reviewing, registering and monitoring compliance of registrants of agvet chemicals, the APVMA may also issue permits and license manufacture. The APVMA's procedures are determined in great detail by the provisions of the Agvet Code, which is set out in a schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.[3]

Proposed amendments

2.5 In the Explanatory Memorandum to the bill the Government stated that the proposed amendments would:

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1 Department of Agriculture, Fisheries and Forestry, *Submission 32*, p. 2.

2 Department of Agriculture, Fisheries and Forestry, *Submission 32*, p. 3.

3 Department of Agriculture, Fisheries and Forestry, *Submission 32*, p. 2.

- Enhance the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations through development, publication and implementation of a risk framework, which the APVMA must have regard to and legislative amendments to align regulatory effort with chemical risk;
- Ensure the ongoing safety of agvet chemicals and improving the effectiveness and efficiency of current agvet chemical reconsideration arrangements by implementing a mandatory re-approval and re-registration regime, designed to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses;
- Improve the efficiency and effectiveness of assessment processes for agvet chemicals applications for approval, registration and variation, and improving the timeliness of agvet chemical approvals, registrations and reconsiderations;
- Improve the ability of the APVMA to enforce compliance with its regulatory decisions by providing the APVMA with a graduated range of compliance enforcement powers and introducing a power to apply statutory conditions to registrations and approvals;
- Improve consistency in data protection provisions and remove disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals; and
- Address perceptions of a conflict of interest by providing for an agency other than the APVMA to collect the chemical products levy, should it be cost effective to do so.[4]

The Bill also includes other amendments to remove redundant provisions and amend out of date provisions.[5]

2.6 In this regard, the Government has identified six areas for improvement, as follows:

- Approvals, registrations, permits and licences;
- Re-approval and re-registration;
- Enforcement;

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4 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, pp 1–2.

5 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, pp 1–2.

- Data protection;
- Levy collection; and
- Other amendments.[6]

Each of these areas is addressed in turn below.

Approvals, registrations, permits and licences

2.7 The approvals process is to be reformed to ensure that applications for approvals or registration are of the required standard to be assessed. The amendments require the APVMA to refuse inferior or deficient applications.

2.8 Applicants would be assisted by the APVMA's principles and processes being made transparent by the publication of a risk framework or compendium. Applicants would also be offered assistance with their applications, for a fee, before they are submitted. It is expected that the new processes will improve the predictability of regulatory decisions.

2.9 The amendments also introduce timeframes for assessment and reconsideration that include the total time elapsed, including the time taken to provide additional information, so that assessments are not frustrated by the late provision of sometimes inadequate information.[7]

Re-approvals and Re-registrations

2.10 The Government has stated that there is now no mandatory requirement for agvet chemicals, once approved or registered, to be reviewed. The amendments will provide for such a scheme.[8] The Explanatory Memorandum states that:

> The scheme provides a greater level of assurance that existing chemicals and products do not pose an undue risk to human health or the environment, and further promotes public confidence in agvet chemical regulation.[9]

2.11 The provisions surrounding the re-approval and re-registration process are canvassed in some detail in Chapter 3 of this report.

Enforcement

2.12 The intent of the amendments relating to enforcement is to provide the APVMA with a range of penalties more appropriate to its regulatory role. New provisions would allow the Authority to impose penalties other than a warning letter or criminal prosecution as is the case at present. The amendments also create new offences, for example, failing to comply with directions of inspectors and failing to

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6 Explanatory Memorandum, pp 2–8.

7 Explanatory Memorandum, p. 3.

8 Explanatory Memorandum, p. 3.

9 Explanatory Memorandum, p. 3.

comply with a notice to produce documents or things or attend an interview to answer questions.

2.13 The Government has stated that the new offences either align with existing offences or are consistent with the Government's *A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers.*[10]

2.14 The amendments relating to enforcement have been considered in some detail by other Parliamentary committees – in Alert Digest No. 1 of the Senate Standing Committee for the Scrutiny of Bills and in the First Report of 2013 of the Parliamentary Joint Committee on Human Rights.[11] See Chapter 3 for further discussion.

Data protection

2.15 Data protection is stated to be a common feature of agvet chemical regulation in countries that have comparable registration systems to that of Australia. According to the Explanatory Memorandum:

> The current data protection provisions are overly complex and do not provide meaningful access to data protection for information provided to a reconsideration. By enhancing data protection provisions, the Bill removes disincentives to invest in innovative product development and to improve the productivity of Australia's agri-food industries.[12]

Levy collection

2.16 The APVMA is funded by the industry through fees, charges and levies on the wholesale sale of agvet chemicals, which are collected by the Authority. The bill would allow for another Australian Government agency to collect the levies if that were cost effective. The amendments are intended to address any perception of a conflict of interest given that the APVMA is both the regulator and collector of fees.

Other amendments

2.17 Other amendments to the current legislation include those that preserve Parliamentary oversight of legislative instruments made under the legislation.

Recent developments in regulation

2.18 In 2006, the Council for Australian Governments (COAG) identified the need for regulatory reform in relation to chemicals and established a Ministerial Taskforce, to 'develop a streamlined and harmonised national system of chemicals and plastics regulation'.[13] COAG also referred the matter to the Productivity Commission for

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10 Explanatory Memorandum, p. 4.

11 Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No. 1 of 2013*, 6 February 2013; and Parliamentary Joint Committee on Human Rights, *First Report of 2013*, February 2013.

12 Explanatory Memorandum, p. 6.

13 Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne, p. III.

advice. In 2008, the Commission published a report, *Chemicals and Plastics Regulation*, that found:

> …the current institutional and regulatory arrangements are broadly effective in managing the risks to health and safety, but are less effective in managing risks to the environment and national security. Efficiency could be enhanced by: national uniformity in some regulatory areas; reducing costs and delays in obtaining regulatory approvals; and attaining economies of scale in regulatory administration.[14]

2.19 In 2009, COAG announced that a Memorandum of Understanding for Chemicals and Plastics Regulatory Reform had been agreed to, and established the Standing Committee on Chemicals, whose role was to co-ordinate, monitor and advise governments on the implementation of reforms identified by the Productivity Commission as necessary.[15]

2.20 The Australian Government's response, a discussion paper entitled *Better Regulation of Agricultural and Veterinary Chemicals*, was published in November 2010.[16] That document identified the need for the development of a Regulatory Impact Statement (RIS) to assess the effect of the proposed reforms. A RIS was published in November 2011.

2.21 The Government published an exposure draft of the bill in November 2011 and a revised draft of the bill in September 2012.

Consultation

2.22 DAFF invited public comment on the discussion paper and on the exposure drafts and received many submissions from industry groups, environmental groups, primary producer associations and Commonwealth, state and territory governments. The submissions were considered and the drafts of the bill addressed many of the issues raised in the consultation process.[17]

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14 Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne, p. XXV.

15 Memorandum of Understanding for Chemicals and Plastics Regulatory Reform, Council of Australian Governments, www.coag.gov.au/node/93, (accessed 4 February 2013).

16 Better Regulation of Agricultural and Veterinary Chemicals, Policy Discussion Paper, Australian Government, Department of Agriculture, Fisheries and Forestry, www.daff.gov.au/__data/assets/pdf_file/0009/1853973/agvet-chemicals-discussion-paper-191110.pdf (accessed 4 February 2013).

17 Department of Agriculture, Forestry and Fisheries, *Submission 32*, p. 8.

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

Coalition Senators' Dissenting Report

1.1 The Coalition Senators do not support the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 in its current form.

1.2 Inherent in this bill is the all too familiar layering of red tape, bringing with it additional costs and further complicating and tangling the workings of business and industry.

1.3 As stated by Mr Matthew Cossey, Chief Executive Officer, CropLife Australia:

> In its current form, this bill will only serve to hinder agricultural productivity.[1]

1.4 This theme was common to much of the evidence presented:

> I do not think there has been an adequate cost benefit analysis done, not a quantitative one. There are big jumps from between $2 million to $8 million that could turn into $20 million. Those costs will come back to the farming community. We are told how lucky we are to sit here and to be able to produce food and fibre sustainably that and our place in the sun will be to feed the teeming millions in Asia and so forth but at the same time we try and put every restriction on being able to compete in a global market. I think this is another example of another shackle that could be imposed that will stymie that competitiveness that we need to work in those global markets.[2]

> The new Bill adds over 200 new pages of legislation for the APVMA to administer and it removes none of the existing legislation.[3]

> …the APVMA has become a barrier to the provision of low-cost products by demanding unnecessary data or a range of common commodities… We are being strangled by the current regulatory environment. This needs to be addressed as a matter of urgency.[4]

1.5 Of particular concern is the requirement for mandatory re-registration of agricultural and veterinary chemicals. This requirement is seen as expensive and developed without a compelling cost/benefit analysis:

> In the absence of the government undertaking a clear analysis of the costs and benefits of the proposed measures within this better regulation process the NFF continues to hold concerns that the proposed changes will impact

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1 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 4 February 2013, p. 35.

2 Mr Reg Kidd, Chair, Agricultural and Veterinary Chemicals Committee, NSW Farmers Association, *Committee Hansard*, 4 February 2013, p. 48.

3 Animal Health Alliance (Australia) Ltd, *Submission 6*, p. 2.

4 Veterinary Manufacturers and Distributors Association, *Submission 24*, p. 1.

> on the costs of chemicals and the availability of chemicals in the Australian market. These impacts will ultimately be felt by the agricultural community and in the productivity and profitability of individual farm businesses.[5]
>
> …the proposed bill increases costs for registrants and applicants. The APVMA's own cost recovery discussion paper associated with the bill already demonstrates that the proposed new registration system will cost an extra 30 per cent. To put the effect of this increased cost in perspective, it currently costs the same real dollar amount to register a crop protection product in Australia as it does in the United States, but the Australian market is one-tenth the size of the market in America.[6]

1.6 The three tiered re-registration methodology suggested by the bill may appear inexpensive with estimated re-registration cost of the lowest tier being $700.

1.7 However, the Majority report concedes that tier 2 assessments 'would require the generation of potentially expensive data and may well cause manufacturers to consider whether to continue to seek re-registration.'[7]

1.8 Even more concerning is evidence provided suggesting how easily re-registration requirements could move from tier 1 to tier 2. While appearing to present a risk based tiered approach to the re-registration process, the potential for abuse is clear and is confirmed in the Majority report where a departmental official indicated that re-registration considerations would progress to the second tier if there is "the sniff of a doubt" at the first stage.[8]

1.9 The potential for re-registration to be escalated from tier 1 based on unfounded, ill-informed social media campaigns rather than sound evidence is clear and has been a hall mark of the current Labor Government, particularly in relation to primary production.

1.10 The Coalition recognises that a consequence of this amendment could be a dramatic reduction in the availability of agricultural and veterinary chemicals, not because use of the chemicals is proven to be unacceptably dangerous to humans or the environment, but for economic reasons:

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5 Mr Matt Linnegar, Chief Executive Officer, National Farmers Federation, *Committee Hansard*, 4 February 2013, p. 46.

6 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 4 February 2013, p. 35.

7 Mr Marc Kelly, Director, Reform Development and Implementation, Department of Agriculture, Fisheries and Forestry, *Committee Hansard*, 4 February 2013, p. 65; and Majority report paragraph 3.26.

8 Mr Marc Kelly, Director, Reform Development and Implementation, Department of Agriculture, Fisheries and Forestry, *Committee Hansard*, 4 February 2013, p. 65; and Majority report paragraph 3.26.

> However, a re-registration/ re-approval program will result in loss of products as approval holders and registrants decide not to supply new data if the APVMA requests new data not required by other regulators.[9]
>
> We are seeing that in the international experience—for example, in the EU approximately half the products ended up off the market through the re-registration process and much of that was due to commercial decisions made by the chemical companies not to take those products forward. In Australia, due to it being a small market, we may even see that sort of issue magnified.[10]

1.11 This in turn reduces the ability of Australian producers to effectively produce the food and fibre that is essential for domestic and international supply:

> …the re-registration process is going to make it very difficult to maintain the existing suite of minor use chemicals that our industry relies on…[11]

1.12 Inherent in evidence provided to the Committee was a level of frustration with the Government response to the consultation process:

> The [Animal Health Alliance] has been active over the last years in attempting to highlight to the Government and DAFF, while drafting the new Bill, the flaws and impediments in the proposed new processes intended to operate to deliver this new Bill.[12]
>
> It would appear that the outcomes of the consultation did not deliver the genuine improvements to the bill as proposed. There has been movement, Senator. To give credit where credit is due, there has been movement. But I am concerned that the focus, as publicly stated, of this initiative at the beginning, which was all about efficiency when the government made the announcement of the review, has not been in fact the focus of the work that has delivered the bill before the parliament.[13]
>
> The point that you make is something that we have put in our submission—that is, about the way the APVMA consults with industry and the need for enhanced consultation with the grower bodies. That is something that we have put down, and a number of grower bodies, through the consultation the department has undertaken and in submissions to the two parliamentary inquiries, have noted that there needs to be enhanced consultation.[14]

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9 Mr Tichon, *Submission 20*, p. 1.

10 Mr Dave McKeon, Manager, Rural Affairs, National Farmers Federation, *Committee Hansard*, 4 February 2013, p. 52.

11 Australian Forest Products Association, *Submission 12*, p. 2.

12 Animal Health Alliance (Australia) Ltd, *Submission 6*, p. 2.

13 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 4 February 2013, p. 36.

14 Mr Justin Crosby, Policy Director, NSW Farmers Association, *Committee Hansard*, 4 February 2013, pp 50–51.

1.13 This amendment is further evidence of the disconnect that exists between the Labor Government, the Greens Party and the Australian farming community. It does not recognise that the means to remove unacceptably hazardous chemicals already exists in the current legislation.

1.14 Instead of requiring what already exists to work more effectively, the Government's solution is to place responsibility and cost on industry and increase the opportunity for manipulation by minority groups.

Recommendation 1

1.15 The Amendment Bill should not be passed in its present form.

Senator the Hon Bill Heffernan
Deputy Chair
Liberal Senator for New South Wales

Senator Fiona Nash
Nationals Senator for New South Wales

Senator Chris Back
Liberal Senator for Western Australia

Senator the Hon Richard Colbeck
Liberal Senator for Tasmania

Senator Sean Edwards
Liberal Senator for South Australia

Senator Anne Ruston
Liberal Senator for South Australia

Australian Greens' Minority Report

1.1 The Australian Greens welcome improvements in the regulation of agricultural and veterinary chemicals however the inquiry identified some areas that requirement amendments in order to improve the effectiveness of this regulation. We therefore cannot agree that the bill should proceed without amendments.

1.2 There is no doubt that some agricultural and veterinary chemicals have damaged human and environmental health and continue to pose risks to both. Risk management should be at the core of any registration program and those chemicals that pose unacceptable and unmanageable risks should not be permitted in Australia.

1.3 We want the approach to risk taken by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to reflect contemporary science in toxicology and regulatory approaches in other countries and we are concerned this is currently not the case.

1.4 There is still too much discretion being given to the APVMA to determine "undue hazard" to the safety of people and the environment without a suitable framework under which to determine that risk. These additional comments outline our concerns and provide recommendations to improve how the APVMA carries out its work.

Conflict of interest

1.5 As a fully cost recovered agency, the APVMA can be placed in a position that gives rise to conflict of interest and is sometimes perceived to be unduly influenced by the agrochemical industry in its decisions.

1.6 The APVMA should come under the responsibilities of either the health or environment ministers, or a combination of the two so that any potential for industry's influence over the APVMA is minimized.

Manageable and Unmanageable risks

1.7 The majority report recognises that many chemistries were 'grandfathered' into the present national scheme and that it is time to conduct a full health and environmental risk assessment. Re-registration is a crucial part of that assessment and the Australian Greens strongly support this work. However the Australian Greens are concerned that this assessment will be compromised by a lack of definition around risk.

1.8 While the objectives recognise 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, there is no definition of 'unmanageable risks' in the Bill or regulations.

1.9 Other organisations focused on manageable risk, essentially approaching the definition problem from the opposite perspective, and the weight of evidence raising concerns about the lack of definition around risk is significant.

1.10 The Australian Greens share WWF's concerns that as the Bill is currently drafted, unmanageable chemicals could still potentially get a 7-year re-approval/re-

registration after a 4.5-year review, which effectively means they could be on the market for another 11.5 years, or possibly longer. In particular the Australian Greens agree with WWF's assessment that:

> In its current form, Schedule 2 is unlikely to quickly remove the backlog of unmanageable chemistries from the market that no longer meet the health and safety standards of today because the Bill fails to define 'unmanageable risks' and it doesn't provide clauses for the implementation of this objective, and the proposed timeframes for review and removal of unmanageable products from the market are far too long.[1]

1.11 This is absolutely unacceptable. It should be a matter of urgency to identify the chemicals that pose unmanageable risk and fast track this work within the first 12 months.

Definition of unmanageable risk

1.12 WWF provide an example of an internationally accepted definition for a highly hazardous pesticide that could be adopted in Australia, while still taking account of unique use and exposure scenarios in Australia:

> Highly hazardous [or unmanageable] pesticides are pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as WHO or GHS or their listing in the annexes of relevant binding international agreements or conventions. In addition, pesticides that cause severe or irreversible harm to health or the environment under conditions of use in a country.[2]

Definition of 'meets the safety criteria'

1.13 The Bill should also give greater clarity as to how a definition of unmanageable risk might trigger action by the APVMA.

1.14 As well as providing a definition for unmanageable risk, WWF suggested including an addition clause at 5A(1)(d) which explicitly references unmanageable risk to ensure that the APVMA can act to address unmanageable risk and would improve the efficiency of the system by ensuring time and resources are not wasted assessing unmanageable risks.[3]

Recommendation 1

1.15 That the Bill includes a definition of unmanageable risk in the objects and the assessment triggers of the Bill.

Toxicity of degradation products and metabolites

1.16 In some instances the degradation products and metabolites of an active constituent, may be more toxic or persistent than the parent compound. If the APVMA

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1 WWF Australia and National Toxic Network, *Submission 25*, p. 2.

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

3 WWF Australia and National Toxic Network, *Submission 25*, p. 6.

are genuinely conducting a risk assessment to determine "undue hazard" to people, animals and the environment, this must be taken into consideration. For the purposes of being satisfied as to whether an active constituent meets the safety criteria, the APVMA must also assess the toxicity of the degradation products and metabolites, of the active constituents. WWF suggested the Bill could be strengthened by including a reference to the toxicity of a chemical's degradation products and metabolites in the safety criteria at 5A(2)(a)(i).[4]

Recommendation 2

1.17 Include a reference to the degradation products and metabolites as part of any reference to toxicity within the safety assessment criteria.

Banned in comparable overseas markets

1.18 Submitters expressed concern about the use of chemicals that have been banned elsewhere but are still used in Australia. Comparable jurisdictions have since banned some of the chemistries still widely used in Australia, because they did not meet contemporary health and environmental standards.

1.19 Paragraph 47A(1)(a) of the Bill *Varying duration-decisions of foreign regulators*, read in association with the Draft Regulations, provide a process to vary approval periods based on the actions of other jurisdictions, but conditions which require more than one foreign country to prohibit the use of a chemical based on a health or an environmental concern are too restrictive.

1.20 Given that the list of *'regulators that are prescribed by the regulations'* in the draft regulations does not include all European Union member states, this section is very limited in its scope. The reason for the exclusion of EU members is unclear because as WWF note:

> Given that the decisions and supporting documents such as risk assessments from the EU are always provided in English, language should not be an issue when considering all EU member countries.[5]

1.21 WWF recommended that when action is taken in any of the jurisdictions prescribed under the regulations to prohibit the use of a chemical, based on health or environmental concerns, 'then that chemical will go to the top of the list in Australia and the registrant will be given notice, following the process in the Bill, that the registration will not be re-approved.'[6]

1.22 The 7 year time frame in Schedule 2, section 47A is also too restrictive. Given that Australia still has pesticides registered that have long been banned in other countries because, after risk assessment, they failed to meet contemporary health and safety standards and the public's expectations, there is no justification why these same

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4 WWF Australia and National Toxic Network, *Submission 25*, p.6

5 WWF Australia and National Toxic Network, *Submission 25*, p.5

6 WWF Australia and National Toxic Network, *Submission 25*, p.5

pesticides should be considered safe to use in Australia because those bans have been in place for more than 7 years.

Recommendation 3

1.23 Strengthen the relationship between actions taken by foreign jurisdictions and Australian decision making.

Onus on chemical companies to prove their products remain safe at regular intervals

1.24 The onus is still on the APVMA to prove safety because no minimum data requirements have been established within Schedule 2, *Re-approvals and Re-registrations* for industry to comply with.

1.25 As a result, the APVMA is reliant on data and testing from the manufacturer and the APVMA does not have explicit powers to quickly remove a chemical or product if there are data gaps in relation to its toxicology or uses in Australia.

Recommendation 4

1.26 Reverse the onus of proof so that chemical companies have to address data gaps in order to maintain registration.

Addressing regulatory burdens

1.27 Some submitters such as the Animal Health Alliance outlined concerns that some chemicals also have to go through a Therapeutical Goods Authority (TGA) registration process. This can result in an extra level of regulatory red-tape that they felt was unnecessary.[7] In future reforms the Government should consider excluding chemicals that have been subject to a TGA assessment from this registration process or introducing some other method of data sharing and decision making that helps streamline this process.

1.28 Other submitters raised concerns about the minor use permits and off-label use.

1.29 While we would not seek to undermine the risk-assessment process, and have some concerns about anything other than the most targeted and clearly specified off-label use, we appreciate some of the concerns of growers such as those raised in the Australian Mushroom Growers Associations and the National Farmers Federations' submissions that touch on regulatory burden.[8]

1.30 In the review process the Australian Greens would like to see included an examination of the minor use and off-label use that looks at ways to ensure that while the registration and assessment processes are rigorous, that the regulatory burdens associated with minor and off-label use on growers is not unreasonably onerous.

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7 Dr John O'Brien, Managing Director, Jurox Pty Ltd, representing the Animal Health Alliance, *Committee Hansard*, 4 February 2013, p. 13.

8 Australian Mushroom Growers Association, *Submission 35*, p. 2; National Farmers Federation, *Submission 31*, pp 2–3.

Conclusion

1.31 In conclusion, this reform is essential, but it is important that the re-registration process and subsequent reviews of chemical use achieve the ultimate goal of managing risk to human life and the environment, and are based on scientific analysis, take account of decision made in other countries and the actions of the APVMA are not hampered in its risk assessments by a lack of data or a lack of definitional clarity. A definition of unmanageable risk will also help focus the review on efficiently and effectively excluding chemicals that present an unacceptable level of harm. The Bill should be amended to address the issues raised above.

Recommendations

Recommendation 1

Include a definition of unmanageable risk in the objects and the assessment triggers of the Bill.

Recommendation 2

Include a reference to the degradation products and metabolites as part of any reference to toxicity within the safety assessment criteria of the Bill.

Recommendation 3

Strengthen the relationship between actions taken by foreign jurisdictions and Australian decision making in the Bill and the regulations.

Recommendation 4

Reverse the onus of proof in the Bill so that chemical companies have to address data gaps in order to maintain registration.

Senator Rachel Siewert
Australian Greens Senator for Western Australia

APPENDIX 1

Submissions Received

Submission Number	Submitter
1	Ms Stella Hondros
2	Dr Alison Bleaney OBE
3	Dr Matt Landos BVSc(HonsI)MANZCVS
4	Summerfruit Australia Ltd
5	Sustainable Agriculture and Communities Alliance Inc.
6	Animal Health Alliance (Australia) Ltd
7	Queensland Conservation
8	North Queensland Conservation Council
9	Friends of the Earth Australia
10	Tasmanian Farmers and Graziers Association
11	Queensland Department of Agriculture, Fisheries and Forestry
12	Australian Forest Products Association
13	Parkinson's Australia
14	Save Our Trees
15	Ms Barbara Smart
16	CropLife Australia
17	ACCORD Australasia
18	Growcom
19	Rural Industries Research and Development Corporation
20	Mr Michael Tichon
21	Australian Dairy Industry Council
22	Sumitomo Chemical Australia Pty Ltd
23	Feed Ingredients and Additives Association of Australia
24	Veterinary Manufacturers and Distributors Association
25	WWF-Australia and the National Toxics Network
26	Alliance for a Clean Environment Inc.
27	AgForce Queensland
28	Ms Susan J. Probert
29	Tasmanian Agricultural Productivity Group Ltd
30	Victorian Farmers' Federation
31	National Farmers' Federation
32	Department of Agriculture, Fisheries and Forestry
33	NSW Farmers
34	Fruitwest
35	Australian Mushroom Growers Association
36	Syngenta
37	Hills Orchard Improvement Group Inc.
38	Ricegrowers' Association of Australia
39	The Hon Peter Walsh MLA

Additional Information Received

- Received on 8 February 2013, from Animal Health Alliance. Answers to Questions taken on Notice on 4 February 2013.
- Received on 12 February 2013, from WWF Australia and the National Toxics Network. Answers to Questions taken on Notice on 4 February 2013.
- Received on 12 February 2013, from Australian Forest Products Association. Answers to Questions taken on Notice on 4 February 2013.
- Received on 13 February 2013, from Department of Agriculture, Fisheries and Forestry. Answers to Questions taken on Notice on 4 February 2013.
- Received on 13 February 2013, from Australian Pesticides and Veterinary Medicines Authority. Answers to Questions taken on Notice on 4 February 2013.
- Received on 13 February 2013, from Department of Agriculture, Fisheries and Forestry. Answers to Written Questions taken on Notice on 4 February 2013.

TABLED DOCUMENTS

- Tabled by Ms Jo Immig, Coordinator, National Toxics Network on 4 February 2013 in Canberra. A list of Australia's most dangerous pesticides.

APPENDIX 2

Public Hearings and Witnesses

4 February 2013, Canberra, ACT

- ADAMS, Mr James David, President and Executive Director,
  Veterinary Manufacturers and Distributors Association
- ARTHY, Ms Kareena, Chief Executive Officer,
  Australian Pesticides and Veterinary Medicines Authority
- BHULA, Dr Rajumati, Pesticides Program Manager,
  Australian Pesticides and Veterinary Medicines Authority
- CHUDLEIGH, Dr David, Director, Regulatory, New Product Development and Scientific Affairs, Zoetis
  Animal Health Alliance (Australia) Ltd
- COSSEY, Mr Matthew, Chief Executive Officer,
  CropLife Australia
- CROSBY, Mr Justin, Policy Director,
  NSW Farmers Association
- DOYLE, Dr Kevin Adrian, National Veterinary Director,
  Australian Veterinary Association
- GARDINER, Dr Ben Charles, President,
  Australian Veterinary Association
- HEATH, Mr Nick, National Manager, Freshwater,
  WWF Australia
- HOLDSWORTH, Dr Peter, Chief Executive Officer,
  Animal Health Alliance (Australia) Ltd
- IMMIG, Ms Joana Liza, Coordinator,
  National Toxics Network
- KELLY, Mr Marc Douglas, Director, Reform Development and Implementation, Department of Agriculture, Fisheries and Forestry
- KIDD, Mr Reg, Chair, Agricultural and Veterinary Chemicals Committee,
  NSW Farmers Association
- KOVAL, Mr Matthew, First Assistant Secretary,
  Department of Agriculture, Fisheries and Forestry
- LINNEGAR, Mr Matt, Chief Executive Officer,
  National Farmers Federation

- MATTHEW, Mr Gavin, Manager, Processing,
  Australian Forest Products Association
- MATTHEW, Mr Neville George, Regulatory Strategy and Compliance Program Manager, Australian Pesticides and Veterinary Medicines Authority
- McGREEVY, Mr Damian Gerard, Chief Executive Officer, McGreevy Consulting
  WWF Australia and the National Toxics Network
- McKEON, Mr Dave, Manager, Rural Affairs,
  National Farmers Federation
- MEADLEY, Mr Bernard, Deputy Chief Executive Officer,
  CropLife Australia
- O'BRIEN, Dr John, Managing Director, Jurox Pty Ltd
  Animal Health Alliance (Australia) Ltd
- PARNELL, Mr Thomas, Assistant Secretary,
  Department of Agriculture, Fisheries and Forestry
- SEYMOUR, Mr Greg, General Manager,
  Australian Mushroom Growers Association
- STAPLEY, Mr Ben, Policy Manager, Crop Protection and Stewardship,
  CropLife Australia
- TICHON, Mr Michael,
  Private capacity
- TWENTYMAN, Dr Bruce James, Deputy Veterinary Director,
  Australian Veterinary Association