The Parliament of the Commonwealth of Australia

Advisory Report on the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

House of Representatives
Standing Committee on Agriculture, Resources, Fisheries and Forestry

February 2013
Canberra

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Foreword

I welcome the opportunity for the House of Representatives Standing Committee on Agriculture, Resources, Fisheries and Forestry to provide an advisory report to the House on the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012. The Bill seeks to make reforms to the approval, registration and reconsideration of agricultural and veterinary (AgVet) chemicals. This will improve the efficiency and effectiveness of the National Registration Scheme (NRS) for AgVet chemicals and products overseen by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The Bill was referred to the Committee by the Selection Committee on 29 November 2012. The Committee subsequently adopted the inquiry and called for written submissions. A public hearing was held in Canberra on 4 February 2013 with a range of stakeholders, some of whom had concerns with the Bill.

The issues raised with the Committee included stakeholders highlighting their concerns that aspects of the Bill would impact the AgVet chemicals sector. Stakeholders highlighted areas including the proposal for a preliminary assessment process and also the proposal for a system of mandatory re-registration and re-approval for AgVet chemicals and products.

The Committee found that the proposed preliminary assessment process has been designed to increase the quality of applications provided to the APVMA. While acknowledging concerns that this process may create some costs for applicants for registration of AgVet chemical and products, the Committee stated that the process would allow the APVMA to concentrate its resources on providing more timely assessments of applications and reduce delays in evaluating deficient applications.

Over the course of the inquiry, the Committee heard that some AgVet chemicals and products had been in use in Australia for well over 40 years. The Committee was concerned that many of these chemicals and products had not been tested against contemporary standards for human, animal and plant health and safety. This underscores the importance of provisions in the Bill for a mandatory system of AgVet chemical and product re-registration and re-approval based on the risk profiles of each chemical or product as determined under guidelines published by the APVMA.

Australia needs to have a robust, systematic and efficient system of AgVet chemical and product regulation. The reforms proposed in this Bill will allow the APVMA to build on its already well-regarded regulatory credentials and ensure Australia retains its international competitiveness in the AgVet sector.

The Committee has recommended that the Bill be passed.

Hon Dick Adams MP
Chair

Membership of the Committee

Chair	Hon Dick Adams MP	
Deputy Chair	Mr Alby Schultz MP	
Members	Mr Darren Cheeseman MP	Mr Rob Mitchell MP
	Mr George Christensen MP	Mr Dan Tehan MP
	Mr Geoff Lyons MP	Mr Rowan RamseyMP* (from 29/11/12)

* Denotes supplementary member, appointed to the Committee for this inquiry only.

Committee Secretariat

Secretary	Mr David Brunoro
Inquiry Secretary	Mr Muzammil Ali
Research Officers	Mr Nathan Fewkes
Administrative Officers	Ms Jazmine Rakic
	Ms Louise Goss

Terms of reference

The Terms of Reference comprise the text of the Bill and without limiting the scope of these Terms of Reference, the Committee has resolved to target a number of key areas for consideration:

- Initial assessment and registration processes (Schedule No. 1 of the Bill), including:
  - ⇒ Factors that affect efficient regulation, including the risk assessment process;

- Re-approval and re-registration of agricultural and veterinary chemicals (Schedule No. 2 of the Bill), including:
  - ⇒ The need for re-approval /and re-registration;
  - ⇒ The process and practical effects (including the financial impacts) for all stakeholders including the regulator;

- International comparisons and trade issues, including the effects on small companies; and

- Consultation processes and outcomes:
  - ⇒ Including intergovernmental consultations.

List of abbreviations

AgVet	Agricultural and Veterinary
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARFF	Standing Committee on Agriculture, Resources, Fisheries and Forestry
the Bill	Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012
BRCWG	COAG Business Regulation and Competition Working Group
Canadian PMRA	Health Canada – Pest Management Regulatory Agency
COAG	Council of Australian Governments
Committee	Standing Committee on Agriculture, Resources, Fisheries and Forestry
DAFF	Department of Agriculture, Fisheries and Forestry
MORAG	Manual of Requirements and Guidelines
MoU	Memorandum of Understanding
NRS	National Registration Scheme
OBPR	Office of Best Practice Regulations

RIS	Regulation Impact Statement
US EPA	United States Environmental Protection Agency
VFF	Victorian Farmers Federation
WWF Australia	World Wildlife Fund Australia

List of recommendations

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Introduction

Referral and Committee Membership

1.1 On Thursday 29 November 2012, the Selection Committee of the House of Representatives asked the House of Representatives Standing Committee on Agriculture, Resources, Fisheries and Forestry (the "Committee") to inquire into and report on the Agriculture and Veterinary Chemicals Legislation Amendment Bill 2012 ("the Bill").[1] In making the referral, the Selection Committee provided the following reasons:

> The new legislation for the chemical regulator has ignored stakeholder concerns and will massively increase regulation, increase the cost of chemical registration by one third or around $8 m, and add another layer of red tape. This is despite the Minister for Finance and Deregulation listing Agvet chemical reform in the 2012 update on the Australian Government deregulation agenda as a key example that will reduce regulatory compliance costs for business and improve their competitiveness.
>
> The reform process was supposed to address two key areas; the cumbersome assessment and registration process to make it more cost efficient for business and to provide industry with timely access to the best and safest crop and animal protectants; and slowness of review of chemicals identified with potential environmental and safety hazards.

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1 House of Representatives Selection Committee, Commonwealth Parliament, *Report No. 73: Private Members' business and referral of bills to committees* (2012), p. 3.

> However the new legislation instead focuses on adding another layer of red tape with an automatic 7-15 year review process. Despite the RIS for the Agvet reform stating that it is envisaged that the numbers of chemicals referred for review broadly equate to the existing numbers of review nominations. [2]

1.2 No date for reporting was provided by the Selection Committee.

1.3 On 29 November 2012, Mr Rowan Ramsay MP, Federal Member for Grey in South Australia was appointed a supplementary member to the Committee for the purposes of the inquiry. [3]

1.4 The Bill was referred to the Senate Standing Committee on Rural and Regional Affairs and Transport by the Senate on the same day. That Committee has also conducted an inquiry and is due to report on 27 February 2013.[4]

The Committees' inquiry

1.5 The Committee adopted the reference from the Selection Committee on 29 November 2012, and subsequently agreed a range of areas on which to focus. These areas, notwithstanding that the text of the Bill comprised the inquiry's Terms of Reference, were as follows:

> The Terms of Reference comprise the text of the Bill and without limiting the scope of these Terms of Reference, the Committee has resolved to target a number of key areas for consideration:
>
> - Initial assessment and registration processes (Schedule No. 1 of the Bill), including:
>   - ⇒ Factors that affect efficient regulation, including the risk assessment process;
> - Re-approval and re-registration of agricultural and veterinary chemicals (Schedule No.2 of the Bill), including:
>   - ⇒ The need for re-approval/and re-registration;

2 House of Representatives Selection Committee, Commonwealth Parliament, *Report No. 73: Private Members' business and referral of bills to committees* (2012), p. 3.

3 Commonwealth Parliament, *Parliamentary* Debates, House of Representatives, 29 November 2012, 13988, (Tony Burke MP, Minister for Sustainability, Environment, Water, Population and Comunities).

4 Senate Standing Committee on Rural and Regional Affairs and Transport, *website* (7 February 2013) < http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=rrat_ctte/ag_vet_chemicals/index.htm>

- ⇒ The process and practical effects (including the financial impacts) for all stakeholders including the regulator;
- International comparisons and trade issues, including the effect on small companies; and
- Consultation processes and outcomes
  - ⇒ Including intergovernmental consultations.[5]

Call for submissions and public hearing

1.6 The Committee called for submissions to be received by 18 January 2013. In all, 15 submissions were received, representing a wide range of relevant stakeholders.

1.7 On 4 February 2013, the Committee invited a number of stakeholders to provide it with further evidence at a public hearing. Stakeholders who appeared before the Committee were:

- Australian Government Department of Agriculture, Fisheries and Forestry;
- Australian Pesticides and Veterinary Medicines Authority;
- National Farmers Federation;
- WWF-Australia;
- National Toxics Network;
- CropLife Australia;
- Grains Research and Development Corporation; and
- Animal Health Alliance.

1.8 A full program, including the names of individual witnesses who appeared before the Committee may be found in Appendix C.

5 House of Representatives Standing Committee on Agriculture, Resources, Fisheries and Forestry, *Terms of Reference* (7 February 2013) <http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=arff/agvet/tor.htm>

2

Background

Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

2.1 This chapter provides background information to the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 ("the Bill"). In particular, it highlights:

- the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) used to regulate agricultural and veterinary chemicals;
- the reform context and development of the Bill; and
- a description of the key provisions of the Bill.

2.2 Agricultural and veterinary chemicals encompass a vast array of chemicals and products. Agricultural chemicals and products have a variety of uses including the protection of crops from weeds, insects and pathogens; the protection of buildings, parks, infrastructure and houses from pests; and the protection of human and environmental health. [1] Veterinary chemicals and medicines encompass vaccines, antibiotics, worm treatments, lice treatments, vitamins and minerals and those used to protect livestock and domestic or companion animals from a wide range of diseases and illnesses.[2]

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1 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 8.

2 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 8.

2.3 The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a statutory agency charged with the 'registration of all agricultural and veterinary chemical products into the Australian marketplace'.[3] The APVMA, formed in 1993, has oversight of the NRS, being the mechanism by which such chemicals are registered.

2.4 The Bill seeks to amend various legislation oversighting the agricultural and veterinary (AgVet) chemicals sector and in particular, makes a range of changes to how AgVet chemicals are regulated and registered. The Bill aims to amend the following Commonwealth Acts:

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

2.5 The Bill's Explanatory Memorandum states that:

> The Bill implements reforms to the approval, registration and reconsideration of agvet chemicals to improve the efficiency and effectiveness of the current regulatory arrangements and provide greater certainty to the community that chemicals approved for use in Australia are safe. The Bill makes it clear that the health and safety of human beings, animals and the environment is the first priority of the regulatory system.[4]

The current National Registration Scheme

2.6 The NRS 'is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities'.[5]

2.7 The Explanatory Memorandum states that:

> The Code Act contains as a schedule to it, the Agvet Code. Under the NRS, the Agvet Code operates, together with the Agvet Code

3 Australian Pesticides and Veterinary Medicines Authority, *About the APVMA* (7 February 2013) < http://www.apvma.gov.au/about/index.php>

4 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 8.

5 Australian Pesticides and Veterinary Medicines Authority, *National Registration Scheme* (19 February 2013) <http://www.apvma.gov.au/about/nrs/index.php>

of each participating territory (that is, each State and the Northern Territory) to constitute a single national Agvet Code applying throughout Australia.

The Agvet Code, among other things, contains the detailed provisions allowing the APVMA to evaluate, approve or register and reconsider active constituents and agricultural and veterinary chemical products, (and their associated labels). The provisions also allow the APVMA to issue permits and to licence the manufacture of chemical products. Other provisions in the Agvet Code provide for controls to regulate the supply of chemical products; and ensure compliance with and enforcement of the Agvet Code.[6]

Reform context and development of the Bill

2.8 This section will provide a brief history of the reports and consultations that led to the present Bill. Independent reports highlighting the need for reform were released beginning in 2006 and culminated in the development of the current Bill. Commenting on the reforms, the Department of Agriculture, Resources, Fisheries and Forestry's submission to the inquiry stated:

> The reforms have been informed by extensive stakeholder consultation. Chemical industry groups, environmental organisations, primary producer associations, Commonwealth, state and territory agencies were all involved in discussions about the Bill.
>
> Three rounds of public consultation were conducted on the reforms and associated Bill. The first round of public consultation occurred from mid November 2010 to early February 2011 about the policy discussion paper, Better Regulation of Agricultural and Veterinary Chemicals ...
>
> Further public consultation with an exposure draft of the legislation occurred from 15 November 2011 to 29 February 2012 ...

6 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 9.

> The Bill was revised and released again as a revised exposure draft in September 2012. The revised Bill included amendments to address issues raised during the previous round of consultation. [7]

2.9 In brief, the reports and consultations leading to the development to the development of the Bill have been as follows:

- ⇒ In 2006, the Australian National Audit Office (ANAO) released a Performance Audit on the Regulation of Pesticides and Veterinary Medicines, making a number of recommendations.
- ⇒ In 2006, the Council of Australian Governments (COAG) identified the need for regulatory reform in the chemicals and plastics area.[8] It subsequently tasked the Productivity Commission to study the area and identify potential reforms.
- ⇒ In 2008, the Productivity Commission presented its report into Chemicals and Plastics Regulation. It proposed a governance framework to address a number of system failures.
- ⇒ These outcomes were translated into a National Framework for Chemicals and Plastics Regulatory Reform, from which a COAG-backed Standing Committee emerged.
- ⇒ Following this, the Australian Government released the Better Regulation of Agricultural and Veterinary Chemicals policy discussion paper to inform the reform agenda.
- ⇒ Several draft Bills were issued and consulted upon. These consultations have formed the basis of the Bill before the Committee.
- ⇒ The Department of Agriculture, Fisheries and Forestry (DAFF) recently completed a consultation on the regulations associated with the legislation. Their findings are yet to be released.

2.10 Each of these major steps are discussed in further detail below. It should also be noted that in addition to these reports and consultations, a Regulation Impact Statement (RIS) was prepared to assist the Australian Government's consideration of the issues. [9] This is discussed later in this report.

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7 DAFF, Submission 2, p. 9.

8 Productivity Commission (2008), Chemicals and Plastics Regulation, p. iii.

9 Department of Agriculture, Fisheries and Forestry (2011) Regulation Impact Statement: Better Regulation of Agricultural and Veterinary Chemicals, p. 46.

Australian National Audit Office report

2.11 In December 2006, the ANAO released an audit report into the regulation of pesticides and veterinary medicines. Findings of the audit included that:

- key programs such as those to monitor the quality of pesticides and veterinary medicines, could have been better administered
- a greater emphasis was required to be placed on the APVMA's compliance program and in completing chemical reviews
- the APVMA was not meeting its obligation to finalise applications within statutory timeframes.

2.12 Overall the ANAO's audit found that the APVMA needed to address some key issues relating to the NRS including reviewing arrangements for sourcing expert scientific advice to inform decisions, and for using state and territory agencies to complete compliance activities on its behalf. The ANAO also suggested improved regulatory arrangements for the chemicals deemed to be low risk.[10]

Productivity Commission Research Report

2.13 In July 2008, the Productivity Commission released its study into Chemicals and Plastics Regulation.[11] The Commission was asked to 'undertake a research study examining the current arrangements for the regulation of chemicals and plastics in Australia'.[12]

2.14 The Commission's report found that chemicals regulation is generally appended onto a range of state and territory legislation dealing with 'public health, workplace safety, transport safety, environment protection and national security'.[13] The Commission found that while these regimes are broadly effective, they are less effective in managing environmental and national security risks.

2.15 The Commission proposed that a governance framework that addresses failures at four levels be implemented to include:

- policy development and regime oversight;

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10 Australian National Audit Office (2006) Report No 14: Regulation of Pesticides and Veterinary Medicines.

11 Productivity Commission (2008), Chemicals and Plastics Regulation, p. iii.

12 Productivity Commission (2008), Chemicals and Plastics Regulation, p. iv.

13 Productivity Commission (2008), Chemicals and Plastics Regulation, p. xxiv.

- assessment of chemical hazards and risks;
- risk management standards setting; and
- administration and enforcement.

National Framework for Chemical and Plastics Regulatory Reform

2.16 Following the Productivity Commission's report, COAG completed a Memorandum of Understanding (MoU) for Chemicals and Plastics Regulatory Reform.[14] The MoU established the COAG Standing Committee on Chemicals. The Committee's role was as follows:

- co-ordinate the implementation of the new governance framework for the regulation of chemicals and plastics;
- monitor the timeliness, effectiveness and consistency of reforms of chemicals and plastics regulation;
- provide advice and make recommendations as appropriate to BRCWG [Business Regulation and Competition Working Group], COAG and relevant ministerial councils on how chemicals and plastics policy initiatives that have cross-portfolio or cross-jurisdictional implications might be best progressed. Ministerial Councils would include:
  - ⇒ the Australian Health Ministers' Conference;
  - ⇒ the Australian Transport Council;
  - ⇒ the Environment Protection and Heritage Council;
  - ⇒ the Primary Industries Ministerial Council;
  - ⇒ the Workplace Relations Ministers' Council; and
  - ⇒ ministers concerned with the security aspects of chemicals;
- provide an ongoing forum for assessing the consistency of chemicals-specific policy settings across the relevant policy areas, including:
  - ⇒ public health;
  - ⇒ workplace health and safety;
  - ⇒ transport safety;
  - ⇒ environment protection; and
  - ⇒ national security;
- oversee a coordinated national approach to regulatory reform of chemicals and plastics and the consistent application of chemical hazard and risk-assessment methodologies and

14 Council of Australian Governments (2009), National Framework for Chemical and Plastics Regulatory Reform, Memorandum of Understanding for Chemicals and Plastics Regulatory Reform (20 February 2013) <http://www.coag.gov.au/node/93>

international standards such as the Globally Harmonised System of Classification and Labelling of Chemicals; and

- support the coordinated development of regulatory proposals that have cross- portfolio or cross-jurisdictional implications, including input into regulatory impact assessments.[15]

Better Regulation of Agricultural and Veterinary Chemicals policy discussion paper

2.17 In November 2010 the Australian Government released the Better Regulation of Agricultural and Veterinary Chemicals policy discussion paper.[16] The discussion paper proposed a set of reforms to 'increase the efficiency and effectiveness of the APVMA and to enable more effective regulation of agricultural and veterinary chemicals'. The reforms were framed around the following objectives:

- protection of human health and the environment;
- alignment of regulatory effort with the degree of risk;
- enabling timely assessments, registrations and reviews;
- addressing gaps in the current regulatory system;
- improving the governance frameworks and operational activities of the APVMA and its regulatory partners;
- improving communication with agvet chemical stakeholders; and
- ensuring the AVPMA's financial viability for the future.[17]

Ongoing regulatory consultations

2.18 Concurrently, DAFF opened consultations on the proposed regulations to accompany the Bill. The proposed regulations include amendments to the:

- Agricultural and Veterinary Chemicals Code Regulations 1995 (Code Regulations)

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15 Council of Australian Governments (2009), National Framework for Chemical and Plastics Regulatory Reform, Memorandum of Understanding for Chemicals and Plastics Regulatory Reform, Section 5.3 (20 February 2013) <http://www.coag.gov.au/node/93>

16 Department of Agriculture, Fisheries and Forestry (2010), Better Regulation of Agricultural and Veterinary Chemicals, Discussion Paper, (20 February 2013) < http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/responses-to-the-discussion-paper>

17 Department of Agriculture, Fisheries and Forestry (2010), Better Regulation of Agricultural and Veterinary Chemicals, Discussion Paper, p. 7 (20 February 2013) < http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/responses-to-the-discussion-paper>

- Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Admin Regulations)
- Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Levy Regulations)

2.19 The consultation document for the proposed regulations notes that:

> The details of the proposed regulations include amendments to:
>
> - support measures in the revised Bill;
> - refine the scope of agricultural chemical products and veterinary chemical products regulated by the APVMA and to implement Council of Australian Government reforms;
> - amend manufacturers' licence conditions, to align with conditions that are currently and routinely applied to licences;
> - address other minor issues that have been identified with the regulations, including removing redundant or unnecessary provisions and addressing some errors.
>
> The proposed regulations only include the following fees and charges related matters:
>
> - fees for re-approval and re-registration applications, including late re-approval and re-registration applications;
> - global joint reviews and 'timeshift' application fees;
> - pre-application assistance fees and rebates;
> - providing for the APVMA to charge registrants, approval holders and permit holders for copies and extracts from records and registers (amendment to current regulation 73);
> - the removal of a redundant fee provision (current regulation 70A).[18]

2.20 This consultation closed on 21 December 2012 and DAFF is in the process of issuing revised regulations based on these consultations.[19]

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18 Department of Agriculture, Fisheries and Forestry (2012), Agriculture and Veterinary Chemicals Legislation Amendments: Details of Proposed Regulations (20 February 2013) <http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals>

19 Department of Agriculture, Fisheries and Forestry (2012), Agriculture and Veterinary Chemicals Legislation Amendments: Details of Proposed Regulations (20 February 2013) <http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals>

Key Bill provisions

Schedule 1

2.21 Schedule 1 considers the issues of approvals, registrations, permits and licences. The Schedule amends the *Agricultural and Veterinary Chemicals Code Act 1994*. The explanatory memorandum provides:

> *Simplification, reorganisation and modernisation of the Agvet Code*
>
> The Bill simplifies, reorganises and modernises the Agvet Code to reduce uncertainty and complexity in the legislation, and improve the operation and understanding of the legislation. The Bill also includes other amendments to remove redundant provisions and amend out of date provisions in all Commonwealth agricultural and veterinary chemical legislation …
>
> *Enhanced consistency and transparency of assessments*
>
> The Bill includes amendments that improve the efficiency and effectiveness of agvet chemical regulation through increased transparency and predictability of decision-making. The amendments provide for the APVMA to make, publish and have regard to guidelines. These are to form part of an overarching risk-based compendium that would be developed, maintained and published by the APVMA. The compendium will improve transparency by detailing all relevant guidelines, standards and methods which would guide regulatory decisions.
>
> The compendium assists in communicating the APVMA's acceptable level of risk and regulatory posture in regulating agricultural and veterinary chemicals. The compendium also allows the APVMA and its regulatory partners to determine the scale of an assessment appropriate to the decision by better matching regulatory effort to risk. Providing a comprehensive reference to the risk assessment process improves the predictability of regulatory decisions, and therefore increases certainty and consistency for applicants and the community …
>
> *Improving assessment efficiency and effectiveness*
>
> The Bill also includes amendments to address concerns about the time taken by the APVMA to complete applications and reconsiderations. The current assessment timeframes do not take into account the total time elapsed for considering an application or finalising a reconsideration (known as chemical review). This does not provide for certainty and predictability in assessment

> timeframes for applicants or the APVMA. In addition, applicants may provide data for the APVMA's consideration at any time. These existing arrangements unnecessarily frustrate the finalisation of assessments for applications and reconsiderations.
>
> The amendments require the APVMA to refuse inferior or deficient applications so that it only needs to assess applications that are of the required standard. The reforms also introduce timeframes for assessments that include the total time elapsed, including the time taken to provide more information. This increases certainty around when applications will be finalised.
>
> The reforms introduce timeframes for reconsiderations (also known to the community as chemical reviews). Along with other reforms to reconsiderations, this assists in reducing the current backlog and provides for consistent and more predictable completion of assessments within appropriate timeframes.
>
> The reforms would ensure that there is no undue impediment to the use of overseas data and assessments by the APVMA, where conducted by comparable agencies and while recognising differences in national approaches. The reforms enable the APVMA to require electronic communication between it and applicants. This electronic communication would also streamline the APVMA's internal administrative processes.[20]

Schedule 2

2.22 Schedule 2 considers re-approvals and re-registrations. The Schedule *amends the* Agricultural and Veterinary Chemicals Code Act 1994. The explanatory memorandum of the Bill provides:

> Australia currently has no requirement for existing agricultural and veterinary chemicals to be regularly reviewed. Australia has an ad hoc reconsideration system whereby chemicals of concern are brought to the regulator's attention by the community, by industry itself or on the regulator's own initiative. This existing approach is not consistent with international best practice.
>
> Consistent with international practice and coupled with Commonwealth funding to mitigate start-up costs, the Bill provides for a mandatory scheme for re-approval and re-registration. Re-approval and re-registration will increase the scrutiny of chemical constituents and products through a scheme

20 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012.

> that minimises impacts on industry. 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.[21]

Schedule 3

2.23 Schedule 3 considers issues of enforcement. The Schedule amends the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, A*gricultural and Veterinary Chemicals (Administration) Act 1992* and *Agricultural and Veterinary Chemicals Code Act 1994*. The explanatory memorandum to the Bill provides:

> The APVMA currently lacks a modern graduated compliance regime. The current legislation provides no intermediate measures between the extremes of warning letters and criminal prosecution. In addition, some provisions limit the APVMA's ability to respond when new information becomes available during the course of an investigation.
>
> The APVMA currently lacks a modern graduated compliance regime. The current legislation provides no intermediate measures between the extremes of warning letters and criminal prosecution. In addition, some provisions limit the APVMA's ability to respond when new information becomes available during the course of an investigation.[22]

2.24 The Bill creates a range of new offence provisions, addresses previous inconsistencies and provides for existing offence provisions to also be civil penalty provisions. The Bill will give the APVMA the power to:

> The Bill includes a number of new offence provisions. The new offences either align with existing or previous offences or are consistent with the *A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers* (published by the Attorney-General's Department).[23]

21 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012.

22 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012.

23 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 4.

2.25 The Bill also:

- Increases penalties in some circumstances 'to ensure that the penalty remains proportionate to the potential gain from non-compliance and to align with the penalties for other similar offences'[24]
- Inserts a new Division that 'provides for the more efficient collation of information to provide a response that is complete and allows persons to consider their rights and obligations and seek appropriate legal advice before providing information, documents or answers to questions'.[25]
- Allows the AVPMA to 'to suspend or cancel, respectively, a registration or a permit where it considers this is necessary to prevent imminent risk to persons of death, serious injury or serious illness. The APVMA may exercise this authority whether or not the product is being used in accordance with its instructions for use or conditions of the permit'[26]
- Provides powers for persons assisting APVMA inspectors
- Allows to APVMA to 'apply to a court to have a person pay certain costs incurred in investigation of the offence or civil penalty provision'[27]
- Amends matters pertaining to infringement notices.

Schedule 4

2.26 Schedule 4 considers data protection. The Schedule amends the *Agricultural and Veterinary Chemicals Code Act 1994.* The explanatory memorandum to the Bill provides:

> Data protection is a common feature of agricultural and veterinary chemical regulation in countries that have comparable regulatory systems to Australia. As investment in regulatory data can require significant resources and because the time taken to collect such data and have it assessed by the regulator diminishes its value, the protection of these data encourages innovation in agricultural and veterinary chemicals. In the case of new chemical products this

24 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 4.

25 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 4.

26 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 5.

27 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 6.

means that the APVMA cannot rely on data it holds to register a product without the data owner's permission and before the protection period has elapsed.

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.

The Bill includes amendments to improve data protection provisions by making them simpler and more consistent, and therefore easier for industry and the APVMA to interpret and for the APVMA to administer. The reforms also reduce the disincentives to generating and providing data by extending data protection eligibility to a greater range of data. In the case of reconsiderations, some amendments have been made to improve the system whereby the data owners and other registrants can share the costs of any data required.

The Bill includes amendments to improve the mechanism by which data owners can obtain compensation for information submitted in relation to a reconsideration. These reforms would more closely align the data protection for new products and reconsiderations, and reduce the disincentive to providing data as part of these reconsiderations.[28]

Schedule 5

2.27 Schedule 5 considers arrangements for collection of the relevant levy. The Schedule amends the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*. The explanatory memorandum to the Bill provides that:

> The Bill amends the current levy collection provisions to allow alternative arrangements to be implemented. The APVMA is one of a number of Australian Government regulators funded by fees, charges and levies imposed on the industry it regulates. Chemical companies pay fees for the APVMA to, for example, evaluate product registration proposals and pay a levy based on the value of wholesale sales of chemical products.

28 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, pp. 6 - 7.

> Amendments in the Bill provide for any Commonwealth agency to be able to issue notices regarding levy assessments and receive levy payments, should it be cost effective to do so. Such a change would allow the government to respond to perceptions of a conflict of interest arising from the current arrangements for collection of this levy. No change to the levy structure or rate is proposed by the Bill.

Schedule 6

2.28 Schedule 6 considers miscellaneous amendments. The Schedule amends the *Agricultural and Veterinary Chemicals Act 1994*. The explanatory memorandum to the Bill provides that the Bill:

> updates the Agvet Act and the Code Act to specifically provide for legislative instruments made under the Agvet Act or the Code Act, including orders, to remain subject to disallowance with two exceptions …
>
> includes provisions that deal with transitional, application and savings measures for amendments made by the Act. To ensure a comprehensive transitional approach can be adopted the Bill provides for regulations to take effect before they are registered and this may have some retrospective application of certain measures. A safeguard measure has been included to ensure that a court must not convict a person of an offence, or order the person to pay a pecuniary penalty, in relation to the conduct on the grounds that the person contravened a provision because of a retrospective effect of the regulations.[29]

29 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, pp. 7 - 8.

3

Issues and Analysis

Summary of key issues

3.1 This chapter will examine the key issues arising from the Committees' inquiry. In particular, it will discuss the issues raised against the areas of focus highlighted by the Committee in earlier chapters. The issues to be considered include:

- the proposed risk compendium and preliminary assessment process;
- the practical impacts of the proposed mandatory re-registration and re-approval process including the potential for increased regulatory burden and costs on stakeholders and impact on users of minor use chemicals;
- international trade issues including the need to be cognisant of the actions of foreign regulators; and
- the impact, analysis and evaluation of the proposed reforms including addressing concerns around cost benefit analysis.

New initial assessment and registration processes

3.2 As highlighted in Chapter 2, the Committee chose to focus on a number of specific aspects of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 ("the Bill"). The first of these was to examine a number of issues in Schedule 1 of the Bill. Of particular concern, two issues were highlighted to the Committee:

- the proposed risk compendium outlining matters for which the Australian Pesticides and Veterinary Medicines Authority (APVMA) must have regard when making decisions; and
- the proposed preliminary assessment process.

Risk compendium

3.3 A key feature of the Bill is the expectation that the APVMA will balance the need to perform its functions as a regulator with the potential risks posed by AgVet chemicals. In this regard, it is proposed that the APVMA 'develop, publish and have regard to guidelines … when exercising powers and performing functions under the AgVet Code.'[1] These guidelines will form the basis of a risk compendium available to stakeholders.

3.4 The Bill provides for the APVMA to make guidelines that include the 'principles and processes for effective and efficient regulation of chemical products and their constituents.'[2] These must have regard to a range of matters including 'guidelines relating to approvals, registrations, permits and licences' as issued by the APVMA. In addition, the Bill also provides for the APVMA to specify the types of information that must be included to constitute a valid application.[3]

3.5 The compendium will build upon the APVMA's current guidelines for AgVet chemicals known as the Manual of Requirements and Guidelines (MORAG), which applies individually to both agricultural and veterinary chemicals.[4]

3.6 A number of stakeholders to the Committee's inquiry have outlined concerns about the use of the risk compendium in making assessments.

3.7 The Hills Orchard Improvement Group Inc's submission states:

> Effective, comprehensive guidelines are essential to providing certainty to applicants about the way their application will be treated. While the current Manual of Requirements and Guidelines is useful, it is not specific nor detailed enough to effectively

1 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 2.

2 Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (Cth) sh 1 cl 28.

3 Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (Cth) sh 1 cl 29.

4 Australian Pesticides and Veterinary Medicines Authority, Manual of Requirements and Guidelines, (7 February 2013) <http://www.apvma.gov.au/registration/morag/index.php >.

> operate as a sufficient guide. APVMA guidelines must also apply to risk assessment advice sought from external agencies.[5]

3.8 CropLife Australia's submission to the inquiry does not support the view that the risk compendium will provide complete predictability of all information required during the assessment process. CropLife Australia suggested that these changes will particularly impact applicants wishing to 'successfully register innovative new active constituents in Australia'. CropLife Australia's reasoning for this was that as the risks associated with newer entities are not always known, applicants making such applications may need to more fully engage with the APVMA—a process which the proposed new timeframe requirements may discourage, leading to the rejection of an application. [6]

Preliminary assessment process

3.9 One of the aims of the Bill is to achieve a higher quality of application to ease both the burden on the regulator and to ensure that applicants meet a minimum standard. The Department of Agriculture, Fisheries and Forestry (DAFF) notes in its submission:

> One of the objectives of the reforms is to place the onus on applicants to ensure their applications are of the required standard to be assessed, instead of inappropriately relying on regulator resources to replace the need for their own expertise.[7]

3.10 Further, DAFF notes in its submission that by utilising a preliminary assessment process, it will reduce the administrative burden on the APVMA and ensure more timely processing of applications.[8]

3.11 In assisting applicants to make valid applications consistent with the specified guidelines, the Bill provides that the APVMA must complete a preliminary assessment process on applications within one month of lodgement by an applicant. The APVMA is to provide applicants with confirmation of the acceptance or refusal of the application within this one month period. The Explanatory Memorandum states that:

> The amendments require the APVMA to refuse inferior or deficient applications so that it only needs to assess applications that are of the required standard. The reforms also introduce

5 Hills Orchard Improvement Group Inc, Submission 5, p. 20.

6 CropLife Australia, Submission 12, p. 7.

7 Department of Agriculture, Fisheries and Forestry, Submission 2, p. 4.

8 Department of Agriculture, Fisheries and Forestry, Submission 2, p. 4.

> timeframes for assessments that include the total time elapsed, including the time taken to provide more information. This increases certainty around when applications will be finalised.[9]

3.12 In conducting the preliminary assessment, the APVMA 'only needs to determine if the application appears to meet the application requirements'[10] and applications must not be refused purely because preliminary assessment has not been completed within the one month timeframe.[11]

3.13 A number of stakeholders highlighted perceived limitations with the preliminary assessment process. In particular, concerns existed over the amount of information that the APVMA is able to consider when determining applications during preliminary assessment and that applicant engagement would be limited in resolving defective applications.[12] For example, in its submission to the Committee's inquiry, Syngenta notes that:

> Despite the immense detail contained in the US and Canadian risk compendiums, it is not possible to predict the exact data or information requirements the US EPA [Environmental Protection agency] or Canadian PMRA [Pest Management Regulation Agency] may require in assessing an application. For this reason both the US and Canadian systems provide scope for applicants to address technical questions during the assessment process.[13]

3.14 Further concerns were expressed that applications could be rejected on the basis that preliminary assessment had not been completed.[14] In its submission to the Committee, Syngenta states:

> … the proposed Bill substantially constrains the manner with which, and the timeframes within which, applicants can engage with the APVMA to provide additional information in support of their application … The Bill and associated regulations will require the APVMA to refuse an application if an applicant is unable to

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

10 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 29.

11 Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (Cth) sh 1 cl 28.

12 See: Hills Orchard Improvement Group Inc, Submission 5, p. 20 and Syngenta, Submission 14, p. 2 and CropLife Australia, Submission 12, p. 6.

13 Syngenta, Submission 14, p. 2.

14 See for example: Hills Orchard Improvement Group Inc, Submission 5, p. 21.

> provide this additional information within the short timeframe specified in the regulations ...[15]

Committee comment

Risk compendium

3.15 Overall, the Committee is supportive of the development and use of a new risk compendium to support assessment of AgVet chemical applications on the basis that it will provide a more systematic and transparent method of assessment. In particular the Committee believes that the development of the risk compendium needs to be practically focussed and transparent to ensure compliance and understanding by stakeholders. The Committee also understands that it is DAFF and APVMA policy to release this documentation prior to the commencement of the legislative provisions.[16]

Preliminary assessment

3.16 The Committee sees the implementation of preliminary assessment to achieve higher quality applications as being a positive step. While the process will shift the onus of compliance to applicants, it will allow the APVMA to concentrate its resources on evaluating applications and reducing assessment timeframes. In this regard, applicants will have the benefit of accessing the proposed risk compendium for guidance on application requirements and standards prior to lodging applications for preliminary assessment.

3.17 In agreeing that this is a positive step, the Committee believes that the APVMA must ensure that all stakeholders are aware of the new preliminary assessment requirements prior to assessments commencing. This should include communicating with clarity about the APVMA's expectations regarding preliminary assessments and ensuring a clear understanding about the types of advice or feedback that is to be provided.

3.18 There is a perception that the APVMA will be able to reject applications should preliminary assessment not be completed within the specified one month time frame. The Committee does not believe this to be correct,

15 Syngenta, Submission 14, p. 2.

16 Department of Agriculture, Fisheries and Forestry (2011) Regulation Impact Statement: Better Regulation of Agricultural and Veterinary Chemicals, p. 44.

noting that the APVMA is only required to determine whether the application meets application requirements.[17]

Mandatory re-registration and re-approval process

3.19 In the interests of providing a more systematic process to regulate AgVet chemicals, Schedule 2 of the Bill proposes a mandatory re-registration and re-approval scheme. The scheme will see active constituents and chemical products reviewed periodically every seven to fifteen years, based on the risk profile to be established in regulations accompanying the Bill.

3.20 This section will examine a number of issues that have been highlighted in evidence to the Committee. In particular, the practical impacts of mandatory re-registration and re-approval will be discussed, with a focus on:

- ⇒ increased regulatory burden on stakeholders;
- ⇒ increased costs on stakeholders; and
- ⇒ the impact of the scheme on minor use chemicals.

3.21 The current system of registration and approval is ad-hoc.[18] It is noted that some chemicals and products used in Australia have never been assessed against modern standards and may have been in use for over 40 years.[19]

3.22 Some 9500 chemicals products and some 2200 active constituents are listed on the NRS (National Registration Scheme).[20] As a result, the Government believes that a systematic method of review is warranted. DAFF justifies the need for this mandatory system, stating that the Bill responds:

> … to community concerns by ensuring that approved or registered chemicals continue to meet appropriate health and safety standards by implementing a re-approval and re-registration scheme to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses.[21]

17 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 29.

18 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 2.

19 WWF-Australia/National Toxics Network, Submission 8, p. 2 and Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 5.

20 Mr Neville Matthew, Australian Pesticides and Veterinary Medicines Authority, Transcript of Evidence, Canberra, p. 3.

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

3.23 Under the Bill, the APVMA must give notice to holders of AgVet chemical and product approvals, with respect to the date the approval ends. This must occur within two years of commencement of the Bill.[22] Once complete, these chemicals and products will be transitioned into the mandatory scheme, where, based on their risk profile, each will be assigned a date for re-registration or renewal over the following seven to fifteen year period. This will mean that for the first time, all registered AgVet chemicals will undergo re-registration and all chemicals products will undergo re-approval.

Practical impacts of mandatory re-registration and re-approval

3.24 Many submissions to the Committee's inquiry made reference to the impacts on industry of the proposed mandatory re-registration and re-approval scheme. In the main, concerns centred around a number of key themes:

- the increased regulatory burden on the AgVet chemicals industry and those who use AgVet chemicals;
- the increased costs for compliance with the new system of re-registration and re-approval; and
- the impacts on producers and users of minor-use chemicals.

Increased regulatory burden

3.25 A number of submissions noted that the new mandatory system of registration and approval would increase the regulatory burden on the AgVet chemicals industry and those that used such chemicals.

3.26 Many submitters saw the reforms as simply adding additional complexity to an already complex system, without removing any existing requirements.[23] For example the Animal Health Alliance notes:

> The new Bill adds over 200 new pages of legislation for APVMA to administer and it removes none from the existing legislation. An additional cost of approximately AUS $8 million is likely to be

22 Mr Neville Matthew, Australian Pesticides and Veterinary Medicines Authority, Transcript of Evidence, Canberra, p. 4 and Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 102.

23 See for example: Australian Forest Products Association, Submission 10, p. 3; National Farmers Federation, Submission 9, p. 2; Accord, Submission 13, p. 4.

> imposed on the agvet chemical industry to implement this Bill in its first year of operation.[24]

3.27 The proposed seven to fifteen year period for re-registration and re-approval of AgVet chemicals was also scrutinised by contributors to the inquiry. In particular, it was pressed that mandatory re-registration would not deliver an outcome of reduced regulatory burden. For example the Victorian Farmers Federation (VFF) states in its submission:

> The goal of regulatory reform should be to reduce needless red tape and improve industry performance. The mandatory re-registration of chemicals every 7 to 15 years will not deliver on this goal. There is the potential this reform will increase the regulatory burden related to agricultural chemicals, impacting the chemical availability for the food producing community.[25]

3.28 The Ricegrowers' Association of Australia's submission states:

> … the proposal appears to betray the fact that APVMA does not have appropriate internal systems in place to maintain an orderly, risk-based system for chemical reviews. Instead of addressing systemic problems affecting the existing review arrangements, APVMA is seeking to impose the burden of its deficiencies on registrants by having every chemical submitted to an automatic process. The regulator is then relieved of the obligation to identify chemicals in need of review using a risk-based process; instead relying on the costly exercise of having each registered chemical pass across someone's desk in APVMA.[26]

3.29 In addition, AgForce Queensland believes that this risk-based timeframe is unrealistic on the basis that it will increase the administrative burden on the APVMA while costs for compliance will be passed onto the end-user of AgVet chemicals.[27]

3.30 DAFF states that in designing the new system for re-registration and re-approval that international best practice has been accounted for, while allowing for unique local variances. Noting the potential burden on industry, DAFF told the Committee:

> we want to try to minimise any burden on the industry and make sure the community actually sees a regular review system for

24 Animal Health Alliance, Submission 1, p. 2.
25 Victorian Farmers Federation, Submission 3, p. 2.
26 Ricegrowers' Association of Australia, p. 3.
27 AgForce Queensland, Submission 11, p. 5.

> chemicals, which is currently missing. This process, for the first time, has that. It removes the ad hoc process for looking at chemicals and it requires the APVMA on a regular basis to look at the inventory of chemicals that are on the market today.[28]

Increased costs

3.31 A number of submissions stated that the mandatory re-approval and re-registration process is likely to result in increased costs for industry stakeholders. For example, the Australian Forest Products Association submitted:

> The additional regulatory processes result in increased costs and inefficiencies for both existing registrants and new applicants, and as a result increase flow-on costs and may limit availability of chemical solutions to industry users.[29]

3.32 In addition, the Hills Orchard Improvement Group Inc's submission advised the Committee that:

> The costs of a re-approval and re-registration mandatory scheme are estimated to be approximately $2 million each year to administer. This figure does not include the costs to applicants which would at least be similar to the APVMA's costs. The question to warrant consideration is will the community see an improvement in health, safety or environmental benefits that make this expenditure worthwhile. There appears little evidence to suggest that this will be the reality.[30]

3.33 CropLife Australia notes that:

> These new processes do not address any regulatory gap. They will not result in improved health or environmental outcomes. They will only add additional unnecessary cost to an already burdensome and expensive registration system.[31]

3.34 The Tasmanian Farmers and Graziers Association's submission to the inquiry states that the Bill:

> … increases costs for registrants and applicants. The APVMA's Cost Recovery Discussion Paper suggests that registrants and

28 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 2.

29 Australian Forest Products Association, Submission 10, p. 2.

30 Hills Orchard Improvement Group Inc, Submission 5, p. 23.

31 CropLife Australia, Submission 12, p. 5.

> applicants will be charged an extra $8 million (around 30%) each year.[32]

3.35 DAFF advised the Committee that the re-registration process does not require the applicant to provide any additional information.[33] DAFF told the Committee that increased costs for applicants would occur where new data was required to be generated in support of an application. DAFF notes that new mandatory re-registration and re-approval scheme would only 'require of the company … information that the company should reasonably be expected to have already', [34] negating additional costs with the exception of an application fee.[35]

3.36 In contrast to this position, the Regulatory Impact Statement prepared as a result of this Bill states that the re-registration and re-approval process:

> would introduce additional costs to approval holders and registrants, who under the existing system are not subject to re-registration requirements. The increased cost to the agvet chemical industry would, however, be outweighed by the benefits to the broader community through improvements to the chemical review program and greater confidence in the integrity of the NRS.[36]

Minor use chemicals

3.37 Submissions to the inquiry have commented that for producers and users of chemicals categorised as 'minor use', the mandatory scheme has the capacity to significantly increase costs and regulatory burden. [37] In some cases, it is suggested that the increase in costs will result in a reduced range of chemicals available for use, as incentives to bring such products to the Australian market will be reduced. [38]

3.38 The National Farmers Federation's submission to the inquiry states that:

> Because of the costs of review, chemical companies may choose not to go through the process of review and chemicals will be

32 Tasmanian Farmers and Growers Association, Submission 6, p. 1.

33 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 6.

34 Mr Marc Kelly, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 6.

35 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 5.

36 Department of Agriculture, Fisheries and Forestry (2011) Regulation Impact Statement: Better Regulation of Agricultural and Veterinary Chemicals, p. 45.

37 See for example: Australian Forest Products Association, Submission 10, p. 2.

38 Agforce Queensland, Submission 11, p. 2.

> withdrawn from the market. This may particularly be the case with chemicals that have low margins or are not widely used. The loss of these chemicals as a consequence of increased requirements for reviews may deny Australian farmers access to chemicals which are actually safe, and may exacerbate issues related to minor and off-label use of farm chemicals. The loss of chemicals may also have flow-on impacts, such as removing options for the management of chemical resistances.[39]

3.39 The Ricegrowers' Association of Australia put forward a concern that in relation to minor-use chemicals:

> Where an emergency minor use permit application is necessary while a registration application is being developed, the APVMA is still permitted to consider the data submitted as part of that application when assessing other permit applications. This doesn't yield the data to anyone else, but makes that applicant commercially uncompetitive against subsequent permit holders who do not bear the same cost of obtaining such data, and provides a massive disincentive to undertake the registration process …[40]

Committee comment

3.40 The Committee understands that a range of AgVet chemicals and products currently used in Australia have not been subject to the rigours of modern scientific analysis to ensure safety. The Committee further understands that many of these products were 'grandfathered' into the current NRS register without scrutiny. For this reason, the Committee believes that the intent of the Bill to ensure that all AgVet products are scrutinised and subject to review is appropriate.

3.41 In terms of the system of mandatory re-registration and re-approval of AgVet chemicals and products, the Committee is sympathetic to the additional regulatory and potentially financial burden that may be imposed on industry and other stakeholders by this process. The Committee believes however that it is important that a balance be struck between the need of the regulator to ensure the continued safety of human, plant and animal health and the ability of industry to continue to deliver new and innovative chemistries and products.

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39 National Farmers Federation, Submission 9, pp. 2-3.

40 Ricegrowers' Association of Australia, p. 4.

3.42 The Committee notes concerns about increased regulatory and cost burden from industry participants caused by these reforms. The APVMA's operation is reliant on recovery of costs reasonably incurred in the registration and approvals process. The Committee understands that industry participants have been actively engaged in their development.[41] The Committee's view is that additional regulatory and cost burden could reasonably be expected to be borne by industry as a consequence of the delivery of a streamlined and more timely system of assessment. Later in this report, the Committee will focus on the importance of evaluation. That will clearly be a process where industry participants can have input into the performance of these reforms.

3.43 The Committee understands the concerns of those AgVet industry participants who rely on 'minor use' chemicals where approval is granted for the limited use of certain chemicals. Understandably the benefits for users of these products will outweigh the commercial benefits for manufacturers and suppliers. In such instances, the Committee believes that the APVMA should take a flexible approach to chemical and product registration and approval where applicable under the provisions of the Bill.

International trade issues

3.44 Australia's agricultural industry relies heavily on the export of its goods, with some 60 per cent of Australia's agricultural product destined for international markets.[42] As such, the international competitiveness of Australia's agricultural industries relies in part on effective regulation of the AgVet chemicals sector to ensure timely exports. As a net exporter of agricultural products, it is also imperative that Australia's agricultural industry complies with the regulatory requirements of countries receiving Australian exports.

3.45 DAFF considers that the Bill:

> … seeks to bring Australia into line with other countries that have similar schemes in a way that complements the specific characteristics of the Australian agvet market, so it delivers the

41 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 6.

42 Department of Agriculture, Fisheries and Forestry Annual Report, 2011-12, inside front cover.

> desired outcomes, without unnecessarily resulting in withdrawal of safe and useful chemicals.[43]

3.46 Mr Matthew Koval of DAFF commented specifically about how Australia ensures that its exports meet the requirements of its international trading partners. Mr Koval stated:

> In terms of international trade … we do use a risk-based system, and it is about trying to make sure that we can argue to our international trading partners that our system is strong, robust and regularly reviewed, and so what we send across to them is of the highest, safest order. When we look at the relevant criteria for the APVMA, they will look at safety, and, at the moment, at efficacy, and they will continue to look at those areas for things where if it works, it is needed, such as vaccines. Also, trade is a relevant matter in the sense of making sure that the use of that product is not going to disrupt international trade and so the re-registration process gives that opportunity to do that in a very quick, low-cost way.[44]

3.47 Given Australia's strong export market, contributors to the Committee's inquiry have raised the issue of why the APVMA has allowed the use of certain AgVet chemicals that have been banned by overseas regulators.[45]

3.48 DAFF responded to a question on this issue at the Committee's public hearing, stating:

> We do use chemicals in Australia that other countries do not and other countries use chemicals that we do not use. It works both ways. That reflects the unique environment of Australia and other jurisdictions. The chemicals that we register and use in Australia are targeted for our unique environment, our operating systems and everything else. Grain fumigants are a perfect example. Due to our climate, we use more grain fumigants than perhaps European countries use. So it is only natural that we have more of those products registered here than they do, because they do not need them.[46]

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

44 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, Canberra, p. 6.

45 See for example: WWF-Australia/National Toxics Network, Submission 8, p. 1.

46 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, 4 February 2013, Canberra, p. 3.

3.49 In making decisions about the use of AgVet chemicals and products that have been banned overseas, DAFF stated:

> … the experience of other regulators overseas with products, and the APVMA then has to go through that and say: 'How is it used overseas? Are their concerns relevant to our concerns here because we have different use patterns or different concentrations and all those types of things?' Also, there might be examples here in Australia where all of a sudden there has been an adverse reaction and so we have to say, 'Hang on a sec, perhaps we need to have another look at that.'[47]

3.50 Dr Rohan Rainbow of the Grains Research and Development Corporation expressed concern that overseas developments may cause adverse judgements to be made with respect to AgVet chemicals and products in Australia. Dr Rainbow told the Committee's public hearing:

> The issues we really wanted to raise were potentially around how the review processes are going on internationally and what impact they might have under this current bill to the way that chemicals are assessed for safety and whether that is approached from a hazard based assessment or a risk based assessment. Under the bill we do see some potential impacts, or legislative triggers … [regarding how] … decisions made in overseas jurisdictions—potentially UK, New Zealand, Canada and the US—will impact in terms of legislative triggers for review here.[48]

Committee comment

3.51 The Committee strongly believes that Australia must maintain an internationally competitive agricultural export sector. The needs of this sector must be balanced against Australia's obligations to its international trading partners (and their respective chemical and product regulatory regimes). It must also be balanced against the requirements of domestic issues, agricultural producers and the community.

3.52 The Committee understands that there are a range of AgVet chemicals and products that have not been removed from the Australian domestic market even though bans on their use exist in comparable overseas markets. The reasons for this include that concerns may not have been

47 Mr Matthew Koval, Department of Agriculture, Fisheries and Forestry, Transcript of Evidence, 4 February 2013, Canberra, p. 8.

48 Dr Rohan Rainbow, Grains Research and Development Corporation, Transcript of Evidence, 4 February 2013, Canberra, p. 31.

raised domestically about their use or that no viable alternative AgVet chemical or product exists for sale to Australian industry.

3.53 The Committee is concerned however that the use of products banned by foreign regulators may threaten the viability of Australian agricultural exports. For example, a country receiving a shipment of Australian agricultural products may reject it on the basis that a chemical banned by regulators in that country has been used during production.

3.54 For this reasons the Committee views that the APVMA must ensure continued collaboration with foreign counterparts. The APVMA must also continue to observe and uphold international best practice when making assessments and enforcing standards for Australian industry.

Consultation, impact analysis, transition and evaluation

3.55 These reforms build on commitments to reform the regulation of the AgVet chemicals industry in Australia. As highlighted in Chapter 2, the Bill has undergone a range of consultative processes, including consultations on the shape of the reforms and the Bill itself. Concurrently, there are also ongoing consultations on the regulations to accompany the Bill. These are in addition to previously highlighted consultations on the APVMA's cost recovery framework.

3.56 In its submission to the inquiry, NSW Farmers emphasised the importance of consultation with both the wider industry and the need to examine how reforms will impact on specific industries. The submission states that:

> … there is a greater need for the APVMA to formally consult with the agriculture industry on its general operation, as well as in specific operations that will impact on industry. In particular NSW Farmers believes that the APVMA should be required to formally consult with impacted industries as part of the reconsideration of a registration/approval.[49]

3.57 Despite the consultations that have occurred, a number of contributors to the Committee's inquiry cited concerns with them. For example, Accord states in its submission to the Committee's inquiry:

> The area of stakeholder engagement which was missing throughout this process however was detailed advice as to why industry suggestions for reform have not been accepted. While a

49 NSW Farmers, Submission 15, p. 2.

> number of modifications were made to the Exposure Bill in light of stakeholder feedback, it is not known why certain recommendations have not been taken up. This feedback loop should be a mandatory part of any stakeholder engagement process.[50]

3.58 In addition, the Australian Dairy Industry Council Inc's submission states:

> The industry also notes that the reform and consultation processes associated with the agvet chemical reforms have involved piecemeal release of documents, lack of a coherent overview of reforms and lack of systematic analysis of costs and benefits of reforms …[51]

Impact analysis

3.59 One of the strongest themes to emerge during the Committee's inquiry was the perception that the consultation processes lacked an assessment of the impact that the proposed reforms would have on industry.

3.60 A range of submissions put forward the view that no discernible cost benefit analysis had been undertaken during the development of these reforms. For example, the National Farmers Federation submission to the inquiry stated that:

> 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 on the costs of chemicals and the availability of chemicals in the Australian market.[52]

3.61 In addition, the Animal Health Alliance's submission to the inquiry states:

> 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 demonstratable cost/risk benefit to warrant such a move.[53]

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50 Accord, Submission 13, p. 6.

51 Australian Dairy Industry Council Inc, Submission 4, p. 2.

52 National Farmers Federation, Submission 9, p. 2.

53 Animal Health Alliance , Submission 1, p. 1.

3.62 In conjunction with the Bill, a Regulatory Impact Statement (RIS) was prepared. The RIS contains an outline of the impacts based on the five key measures proposed.[54] While it is not proposed to conduct a full analysis of the conclusions drawn in the RIS in this report, it should be noted that the RIS was assessed as being compliant with 'the best practice regulation requirements' by the Office of Best Practice Regulation (OBPR).[55]

3.63 One specific concern was that the reforms lacked quantitative cost benefit analysis or a macroeconomic analysis of the impact of the reforms on the sector.[56] In particular, CropLife Australia's submission states:

> Without a clear understanding of the costs and benefits that will accrue from implementation of the proposed reforms, CropLife is concerned that more regulation will result in significant additional costs on a key agricultural supply industry without generating any benefit associated with that cost …
>
> CropLife's own investigations indicate that the potential ongoing costs from additional regulation are likely to be significant and any benefit either small or non-existent …
>
> CropLife strongly recommends that a cost and benefit analysis must be conducted to identify the net impact of these reforms, not only on the agricultural chemical industry, but also on key agricultural industries that rely on modern crop protection tools to remain competitive and productive.[57]

Transitional arrangements

3.64 A number of stakeholders to the Committee's inquiry have suggested that the APVMA may not be ready to implement arrangements as proposed in the Bill.

3.65 NSW Farmers indicated concerns that the APVMA will not be ready for the stated commencement date of the Bill.[58] Particularly in relation to the

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54 Department of Agriculture, Fisheries and Forestry (2011) Regulation Impact Statement: Better Regulation of Agricultural and Veterinary Chemicals, pp. 14-40.

55 Department of Finance and Deregulation, Better Regulation of Agricultural and Veterinary Chemicals (21 February 2013) <http://ris.finance.gov.au/2011/11/29/better-regulation-of-agricultural-and-veterinary-chemicals-%E2%80%93-regulation-impact-statement-%E2%80%93-department-of-agriculture-fisheries-and-forestry/>

56 See for example: National Farmers Federation, Submission 9, p. 2.

57 CropLife Australia, Submission 12, p. 5.

58 NSW Farmers, Submission 15, p. 2.

mandatory re-registration and re-approval the Victorian Farmers Federation states:

> We are also concerned with the potential resources required by the APVMA to maintain this reregistration program will be much higher than in the past. In particular, it was mentioned that for this reform to be a success there would need to be a culture and resource shift within the APVMA. If the success of the new system hinges on significant changes within APVMA there needs to be considerable resources provided to APVMA to facilitate the shift and proof delivered by APVMA that they are prepared to take on this expanded role.[59]

3.66 CropLife Australia's submission to the inquiry states:

> The agricultural chemical industry is now preparing applications and submissions for assessment by the APVMA after July 2013. It can take many months to prepare all the necessary paperwork for applications and to conduct all the required research and trial data to support a particular use pattern. Applicants are doing this without any certainty as to how their applications will be assessed by the regulator.[60]

3.67 In responding the these concerns, Ms Kareena Arthy, Chief Executive Officer of the APVMA told the Committee:

> … the APVMA has been provided with additional resources which will continue. With that we are aiming to have a basic level of preparedness for 1 July and then we will continue working with industry thereafter in terms of implementing the new system.[61]

3.68 The Bill proposed a range of measures that will allow the APVMA to manage the backlog of existing applications. The Explanatory Memorandum states:

> that the requirements in the old Code continue to apply for 12 months to an application lodged with the APVMA before commencement … After this 12 month period, the requirements in the new Code apply, including the timeframes and that the

59 Victorian Farmers Federation, Submission 3, p. 2.

60 CropLife Australia, Submission 12, p. 5.

61 Ms Kareena Arthy, Australian Pesticides and Veterinary Medicines Authority, Transcript of Evidence, Canberra, p. 2.

> APVMA must refuse applications if an applicant does not respond in specified timeframes.[62]

Evaluations

3.69 An important aspect of any new framework is that it is appropriately and adequately reviewed. The Bill includes provisions for a review to be conducted five years from the date of commencement of all provisions of the Bill.[63] Section 4 of the Bill states:

> Section 4 requires the Minister to cause a review to be conducted of the operation of the amendments made by this Act and any other matter specified by the Minister. This section also specifies certain requirements for this review. These include requirements for an independent person to be involved in the conduct of the review and a requirement for public submissions to be sought. This section also requires a report of the review to be laid before each House of Parliament within 15 sitting days of all the provisions in this Act having been in place for five years.

3.70 In addition, the Bill also institutes a review of all Commonwealth legislation about AgVet chemicals at least every ten years. [64]

3.71 A number of submissions to the Committee's inquiry have been supportive of the reviews specified in the Bill. For example, the submission from the Victorian Farmers Federation states:

> The VFF is supportive of a review after five years of operation. This review should include the appropriateness of the Act and also the performance of APVMA in delivering an efficient reregistration process and overall impact of the industries reliant on agricultural and veterinary chemical use. It should aim to answer questions such as:
>
> - What has [been] the net impact of regulation cost for chemical registrants?
> - What has been the overall impact on chemical availability?
> - Is there proof that the new regulatory regime to providing better outcomes for the community and industry?[65]

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62 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 102.

63 Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (Cth) cl 4.

64 Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (Cth) sh 6 cl 33.

65 Victorian Famers Federation, Submission 3, p. 3.

3.72 The Australian Dairy Industry Council Inc's submission discusses the importance of reviews, noting:

> The dairy industry also notes the importance of mechanisms for review of the bill to ensure the measures operate as intended and remain appropriate. These should look at the impact of reforms of chemical availability and cost to identify whether unintended consequences (such as loss of generic or niche products) and occurring, and if reforms require modification.[66]

Committee comment

3.73 In addressing concerns around consultation, the Committee would like to acknowledge the extensive process that has been undertaken in the development of the Bill. It is clear that both DAFF and APVMA have worked with stakeholders for some years with the aim of developing a clearer, more robust and more streamlined system of AgVet chemical and product regulation.

3.74 Although perhaps ideal, and in noting the comments of some contributors to the inquiry, the Committee does not believe that it is common during regulatory consultations for explanations to be provided as to why suggestions made by industry were not adopted.

3.75 The Committee is conscious of the impact that the overall process of reforming AgVet chemical and product regulation will have on industry. Many impacts will be positive such as the proposed preliminary assessment process that will assist in increasing the timeliness of application assessment.

3.76 Regarding impact analysis, the Committee is satisfied that the RIS, as approved by the OBPR was completed adequately and appropriately. The Committee acknowledges that there has been a lack of quantitative analysis to assess the potential impacts however the Committee does not see the need for an extensive macroeconomic study.

3.77 The Committee recognises the significant undertaking that will be required by the APVMA in implementing the new regulatory arrangements. In particular, the Committee notes comments by stakeholders highlighting concerns that the APVMA will not be prepared to process applications under the new arrangements while continuing to process the backlog of existing applications. The Committee hopes that this will not be the case given the additional resources provided to the

66 Australian Dairy Industry Council Inc, Submission 4, p. 1.

APVMA and the extensive preparation undertaken by it to date. The transitional period prescribed in the Bill, providing a 12 month period in which to assess applications under previous arrangements, will also assist in reducing any backlog.

3.78 In concluding, the Committee would like to emphasise the importance of the evaluations that have been integrated into the Bill. At each of these periods, the Committee would expect that the Government would call upon industry stakeholders to provide it with assessments as to the impact of the measures proposed in the suite of AgVet chemicals legislation. This process will result in a more robust system of AgVet chemical and product regulation and will be able to better assess the true costs and benefits of these reforms.

4

Conclusion

4.1 The Committee is of the view that these reforms must provide a balance between the requirements of those in the AgVet chemical industry, the needs of the regulator and the community concerns that have been identified. The Committee believes that the provisions of the Bill are an appropriate starting point from which to proceed. However, the Committee reiterates its previous comments in this report relating to the need for analysis of the impact of reforms and the need for evaluation.

4.2 The Committee views the process of AgVet chemical reform as one of continuous improvement. Given a number of concerns raised by stakeholders in the Committee's inquiry, the need for ongoing discussion between all parties is paramount. If continued discussions not do not alleviate concerns, more frequent evaluations in addition to those specified in the Bill, particularly of the mandatory re-registration and re-approval system, may be warranted.

4.3 The Committee wishes to highlight matters in relation to the Bill recently addressed by the Parliamentary Joint Committee on Human Rights.[1] In particular, the Human Rights Committee is concerned that the powers in the Bill relating to monitoring and investigatory powers are an encroachment on human rights. The Human Rights Committee notes its intention to seek clarification from the relevant Minister as to whether some civil penalty and reverse onus offences are consistent with the International Covenant on Civil and Political Rights (ICCPR).[2]

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1 Parliamentary Joint Committee on Human Rights, Commonwealth, *Examination of Legislation in accordance with the Human Rights (Parliamentary Scrutiny) Act 2011, Bills Introduced 19 - 29 November 2012 and Legislative Instruments Registered with the Federal Register of Legislative Instruments 17 November 2012 – 4 January 2013* (2013), p. 4.

2 Parliamentary Joint Committee on Human Rights, Commonwealth, *Examination of Legislation in accordance with the Human Rights (Parliamentary Scrutiny) Act 2011, Bills Introduced 19 - 29*

4.4 There are currently three federal parliamentary committees that have or will examine this issue from a range of perspectives. The Committee views that the Australian Government should consider the concerns raised in each committees' report in implementing the Bill and in proceeding with wider reforms.

Recommendation 1

The Committee recommends that the House of Representatives pass the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 without amendment.

Dick Adams MP

Chair

5

Dissenting Report

Advisory Report on the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

5.1 The dissenting members have declined to support the majority recommendation of the committee:

> That the House of Representatives pass the Agricultural and Veterinary Chemicals Legislation Bill 2012 without amendment.

5.2 The dissenting members believe reform of the APVMA is overdue and are supportive of a number of the clauses dealing with the procedure and timeliness of APVMA responses to pesticide applications.

5.3 However we believe one of the bills key modifications; the intention to install a system of mandatory re-registration lacks sufficient justification and is likely to create a new layer of compliance and bureaucracy on the pesticide and veterinary medicines industry without demonstrable improvements in efficiency or outcomes and that extra costs will be passed along to Australian farmers.

5.4 The bill states one of its objectives (Key Provisions) is to reduce time-frames for processing applications and admits to backlog in processing:

> this assists in reducing the current backlog and provides for consistent and more predictable completion of assessments within appropriate timeframes".

5.5 It is of great concern to the dissenting members that the proposed mandatory re-registration process will lead to a far heavier work-load for

the APVMA and this in turn will lead to longer delays in processing, an escalation in staffing requirements and a more expensive system for little perceived gain.

5.6 The dissenting members are also greatly concerned that the department has not undertaken a cost/benefit analysis and so consequentially has little understanding of the compliance costs that will be borne by industry outside the direct administrative load. In this case the Parliament is being asked to endorse a new registration regime without understanding the full cost implications for the industries involved.

5.7 The Coalition has announced it is committed to reducing red tape and cost for business in Australia and the support of a mandatory re-registration process is not consistent with that principal.

Key issues

- While all involved in the process agreed that reform was needed to improve efficiency and speed up the review of high risk chemicals, the recommendation to pass the bill fails to adequately consider and address the valid concerns raised by grower groups and industry.
- The Bill fails to meet the efficiency test. The Department of Agriculture, Forestry and Fisheries have not undertaken a cost benefit analysis on the implications of the bill.
- The case for mandatory re-registration was not made as no specific evidence was presented of systemic failure in the current process for the ongoing registration of chemicals.
- There are significant extra costs of mandatory re-registration. The argument that additional activities could be undertaken within current staffing levels was unconvincing with the obvious burden of re-registration.
- The re-registration process doesn't target the risk and actually detracts from the regulators ability to do its job.
- Concerns were raised about re-registration of products with small niche markets that the profits derived from sales would not be sufficient to justify registration and Australian farmers would lose possibly irreplaceable tools.
- Proposed time frames are unlikely to be achievable.

Improvement in efficiency needed

5.8 Reforms were supposed to improve the efficiency of the review of suspect chemistries, reduce cumbersome assessment and registration processes and be more cost-efficient to provide industry with timely access to the best and safest crop and animal protectants.

5.9 These views were widely expressed in submissions and at the hearing.

> "We would agree with the WWF that a greater responsiveness from the regulator in this space would be a very good thing and something that is supported by our members".[1]

5.10 *And* the ANAO's inquiry into the APVMA demonstrates that the APVMA is not as efficient in the way that it conducts its work as it could be.

> The APVMA is also not meeting its obligation to finalise all applications within statutory timeframes. This increases the cost of regulation, for both the APVMA and applicants, and impacts on users' access to pesticides and veterinary medicines.[2]

5.11 This is supported by the WWF

> What we are saying is, 'Trigger a very fast process where those differences between Australia and Europe, or Australia and America—or wherever it may be—make it be considered and a resolution found very quickly.[3]

The Bill fails to prove improvements in efficiency

5.12 Consistent concerns were raised with the legislation's ability to improve efficiency:

> In fact this bill actually increases regulatory burden on the industry and imposes more work on the APVMA without any demonstrable cost/risk benefit to warrant such a move.[4]

1 Public Hearing, Cossey Croplife, p.24.
2 page 19: http://www.apvma.gov.au/about/reporting/docs/anao_audit_report_2006.pdf
3 Public Hearing, Heath WWF, p.17.
4 Public Hearing, Holdsworth, Animal Health Alliance.

> ..introduces additional processes and procedures without any corresponding improvements in regulatory efficiency or environmental or human health protection.[5]

> We are concerned that the overall benefit to the industry will be outweighed by the increase in red tape and regulatory costs associated with the re-registration process.[6]

The case for mandatory re-registration

5.13 The ANAO's inquiry into the APVMA has confirmed that we have an excellent technical and scientific regulatory system for effective management of risk:

> The ANAO concluded that the APVMA has reasonable arrangements in place to identify chemicals that require review and to prioritise the reviews according to the risk they represent.
>
> APVMA do look at what is happening around the world and if there are concerns raised about a particular chemical they do actually act and with the current review process they do that. There is a system to make sure that, if a concern is raised somewhere else in another jurisdiction or within this jurisdiction, we do look at it.[7]

Extra costs from re-registration

5.14 The dissenting members support the majority of submissions that advocate the Government's bill will raise costs and not provide sufficient gains in efficiency.

5.15 The Department does not deny there will be extra costs and this is despite Finance and Deregulation Minister Penny Wong using Agricultural and Veterinary Chemical Reform as the second key area where the government would reduce regulatory compliance costs for businesses and improve competitiveness.[8]

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5 Submission 012, CropLife, Australia, p.2.

6 Submission 003, Victorian Farmers Federation p4.

7 Public Hearing , Koval, DAFF p2.

8 Page 5 http://www.finance.gov.au/deregulation/docs/australian-government-deregulation-agenda.pdf

5.16 It is clear that the Department has under emphasised the extra costs

> The cost is that the maximum is $100 a year; $700 is what we are talking about in the draft legislation for the parliament's consideration. So, if it is a 15-year re-registration period, it is not a huge cost. But that is a commercial decision.[9]

5.17 While as the industry explains there is much more to the costs than just the registration costs.

> The APVMA's own documentation in their cost-recovery paper indicates that we are looking at an increase in the cost of the system for the proposed legislation. In fact, the 30 per cent number is the interim. They have indicated that they will probably have to do another one. Equally, the costs that DAFF were referring to are the straight-up application fees. We know that a large amount of the resourcing for this will be supported by the levies, so to suggest that the costs will be restricted just to re-registration fees does not indicate the true costs, even just to the regulator. Aside from that, administrative processes, while simple, come at a cost. If you have the regulator about to have hundreds upon hundreds of re-registrations, just to manage, file and respond to those re-registrations costs money and it takes resources away from the core input.[10]

> The bill, in its current form however, will deliver a net loss in efficiency and cannot be said in any way to address the system's failure to function within statutory timeframes. CropLife shares the concerns expressed by the farming sector, state governments and a range of other community and industry organisations that this bill, if implemented in its current form, will have a disastrous effect on agricultural productivity in Australia.[11]

5.18 The Members on this dissenting report are especially disappointed the Department Officials in the hearing admitted that the Regulatory Impact Statement failed to quantify the financial costs and financial impacts on industry. Instead it based its decision that the:

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9 Public Hearing, Koval DAFF, p.7.

10 Public Hearing, Cossey Croplife, p.26.

11 Public Hearing; Cossey; Croplife, p.23.

> …benefits outweighed the costs of the system. But it was done in a qualitative sense and not a financial sense.[12]

5.19 The APVMA's own analysis on the system demonstrates extra costs without being able to quantify any improvements due to the re-registration process.

> The APVMA's own documentation in their cost-recovery paper indicates that we are looking at an increase in the cost of the system for the proposed legislation. In fact, the 30 per cent number is the interim.[13]

Efficiency

5.20 Furthermore while delivering a net loss in efficiency it will increase regulation without targeting the risk areas:

> Yes, we would agree with that. As was indicated earlier, there are a number of products on the market that carry a higher risk profile and, in fact, the focus should be there. That is directly counter to the proposition of a re-registration system. The Productivity Commission in its review many years back indicated that that is the type of system you want: not an arbitrary across-the-board re-registration system but one that targets resources specifically to where the highest risk is. We wholeheartedly agree with that, and that in itself will add efficiency.
>
> To add an entire extra level of what is, in the first case, a pure administrative process will obviously take resources away from the regulator and does not look to target those higher-end ones. Again, what we go back to is that the regulator has the powers it needs to address those risk issues. It is really about not adding more regulation—300 pages, as we have counted—but perhaps using other methods to get the regulator able to better respond in that space.[14]

12 Public Hearing, Parnell DAFF, p.9.
13 Public Hearing, Cossey CropLife, p.27.
14 Public Hearing, Cossey Croplife, p.24-25.

Re-registration

5.21 Specifically the Coalition objects in the strongest terms to the re-registration process which acts contrary to the primary aim of the bill to improve the efficiency of the chemical regulator and speed up identification and review of suspect chemicals. This is supported by the Productivity Commission report into chemicals and plastics regulation.[15]

5.22 Recommendation 8.1 states:

> The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:
>
> - the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned,
> - its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.

5.23 The costs of the re-registration process will most likely, result in the loss from the Australian market of useful products that are safe and effective and have been used so for decades.

> Contrary to the government's claims that the re-registration process will increase the scrutiny on suspect chemistries, the increase in the administrative workload of the APVMA staff will reduce regulatory body resources available to deal with critical registrations and permits.[16]

Minor registrations

5.24 Considerable concern was raised with the size of the Australian market and the consequent incentives for potential licensees to register new or re-register safe, old, off-patent chemicals for use.

> …….. the reduction of products on the market is not because of their safety concerns or human health and environment concerns but is very much a commercial decision made on behalf of the chemical companies to not go through the re-registration process.

15 http://pc.gov.au/projects/study/chemicals-plastics/docs/finalreport

16 Submission 11, AgForce Queensland, p.5.

> So many products are moved off the market for purely commercial reasons by those organisations.[17]

5.25 Internationally our registration process is already struggling to compete and that is one of the key reasons the government sought reforms to make it more efficient. Increasing the costs will further reduce our competitiveness and force international companies to evaluate whether the costs and returns will justify the expense.

> To put the effect of this increased cost into 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 American market. Increased cost of registration, combined with provisions that unnecessarily increase the complexity of the regulatory system, will result in the loss of existing agchem products and discourage the introduction of newer, modern chemistry and biological products. In particular, greater regulatory costs will deprive farmers of crucial products that only have small markets, such as for minor uses and specialty crops. I know that that was mentioned just earlier and we will surely come back to that later.[18]

5.26 Small markets size already limits chemical registration in Australia because it is not economically justifiable for chemical companies and a system which increases costs through the re-registration process will further exacerbate this issue.

> The vegetable market would be the best example right around Australia. There are chemicals that are available for broccoli and other crops that are not registered here in Australia because the broccoli market in Australia is not all that big so they do not get registered. You get fewer broccoli producers so we have more imports of broccoli into Australia.[19]

> From a global perspective, for our grains industry and our ability to invest in the market failure gaps, issues around market failure particularly in this very small Australian market—we probably represent less than one per cent of the global pesticide sales—become a real challenge for us.

17 Public Hearing, McKeon NFF, p14.

18 Public Hearing, Cossey Croplife, p.23.

19 Public Hearing, Kidd NSW Farmers, p.13

5.27 and

> In Europe they have taken the decision to look at a hazard based assessment method to assess the inherent hazard of the product against particular criteria. Essentially, during the last 10 years, they have gone from 945 pesticide actives in the late 90s to about 336 in 2009, so there has been a large reduction in those against those hazard criteria. Unfortunately, a large percentage of those were eliminated because the data packages that were required to support the continued use of those products were essentially too expensive for the companies. They could not recoup on investment and so unfortunately packages were not submitted and a lot of the registrations just lapsed.
>
> Australia is a much smaller market than Europe, as you can imagine, for pesticides. The risks of course are that if we go down that particular pathway, while it is absolutely proper and appropriate to use risk based assessment, we need to look at the risks of the products and whether they are acceptable for human health and the environment, and work through that process. Unfortunately, because of the lack of investment and market failure, we have seen the acceleration of the loss of those products.[20]

Timeliness

5.28 Finally outside the re-registration process there is still scope to work with Industry and make further improvements in efficiency that will deliver tangible outcomes in efficiency and help the regulator meet its statutory timeframes. Some of the changes in Schedule 1 have been implemented purely to help the regulator meet statutory timeframes but will as a result likely retard the Industries ability to deliver new safer chemistries onto the market.

> "The rigid processes and constraints proposed in Schedule 1 of the Bill will largely remove any opportunity for an applicant to engage with the APVMA over the duration of an assessment and to provide clarifying information/data to address evaluator's questions as they arise. Similarly, the short extension periods

20 Public Hearing, Rainbow GRDC, p.31

proposed under the "maximum extended assessment periods" in the draft regulations are likely to prohibit the generation of additional data to address unforeseen information requests. These provisions are likely to condemn applications with minor data deficiencies to rejection, or alternately require applicants to pay considerable additional fees in cases where the APVMA elects to vary the application under Section 28(4)".[21]

Conclusion

5.29 In Conclusion this Bill as is drafted provides a substantial increase in regulatory burden and costs that will have a negative impact on industry without significantly improving the efficiency of regulation and the re-registration process will slow down rather than increase the review of suspect chemistries. To achieve genuine efficiencies within the system that allow for a more timely review of suspect chemistries it is vital that the proposed re-registration process be removed from the bill.

Recommendation 1

Remove the re-registration process from the bill

Recommendation 2

Set up a troika taskforce of Industry, the Department and the APVMA to urgently evaluate and improve the internal systems within the APVMA to increase the regulators efficiency and effectiveness and the speed of review of at risk chemistries.

21 Submission 014, Syngenta, p

Mr Alby Schultz MP
Deputy Chair
Liberal Party of Australia,
Member for Hume, NSW

Mr Rowan Ramsey MP
Liberal Party of Australia,
Member for Grey, SA

Mr George Christensen MP
The Nationals,
Member for Dawson, Qld

Mr Dan Tehan MP
Liberal Party of Australia,
Member for Wannon, Vic

A

Appendix A - Submissions

1 Animal Health Alliance (Australia) Ltd
2 Department of Agriculture, Fisheries and Forestry
3 Victorian Farmers Federation
4 Australian Dairy Industry Council Inc.
5 Hills Orchard Improvement Group Inc.
6 Tasmanian Farmers and Graziers Association
7 Ricegrowers' Association of Australia Inc
8 World Wildlife Fund Australia
9 National Farmers' Federation
10 Australian Forest Products Association
11 AgForce Queensland
12 CropLife Australia
13 Accord
14 Syngenta
15 NSW Farmers

B

Appendix B - Exhibits

Australian Forest Products Association

1 *Australian Forest Products Association*

CropLife Australia

2 *Submission in response to Policy Discussion Paper 'Better Regulation of Agricultural and Veterinary Chemicals' (20 December 2010) (Related to Submission No. 12)*

3 *Supplementary submission in response to Policy Discussion Paper 'Better Regulation of Agricultural and Veterinary Chemicals (3 February 2011) (Related to Submission No. 12)*

4 *Exposure Draft – Agricultural and Veterinary Chemicals Legislation Amendment Bill (29 February 2012) (Related to Submission No. 12)*

5 *Second Exposure Draft – Agricultural and Veterinary Chemicals Legislation Amendment Bill (22 October 2012) (Related to Submission No. 12)*

6 *Review of APVMA Cost Recovery Discussion Paper prepared for CropLife Australia (16 February 2012) (Related to Submission No. 12)*

7 *Review of APVMA Cost Recovery Discussion Paper Addendum prepared for CropLife Australia (14 June 2012) (Related to Submission No. 12)*

C

Appendix C – Public Hearing

Monday, 4 February 2013 – CANBERRA

Department of Agriculture, Fisheries and Forestry

Mr Matthew Koval, First Assistant Secretary, Agricultural Productivity Division

Mr Thomas Parnell, A/g Assistant Secretary, Livestock Industries and Agvet Chemicals Branch

Mr Marc Kelly, Director, Agvet Chemical Reform Development and Implementation

Australian Pesticides and Veterinary Medicines Authority

Ms Kareena Arthy, Chief Executive Officer

Mr Neville Matthew, Program Manager, Regulatory Strategy and Compliance

National Farmers' Federation

Mr Matthew Linnegar, Chief Executive Officer

Mr Dave McKeon, Manager, Rural Affairs

Mr Reg Kidd, Chairman, Agricultural and Veterinary Chemicals Committee

Mr Justin Crosby, Policy Director

World Wildlife Fund Australia

Mr Nicholas Heath, National Manager – Freshwater

National Toxics Network Inc.

Ms Joanna Immig, Coordinator

CropLife Australia

Mr Matthew Cossey, Chief Executive Officer

Mr Bernard Meadley, Deputy Chief Executive Officer

Mr Ben Stapley, Policy Manager – Crop Protection and Stewardship

Grains Research and Development Corporation

Dr Rohan Rainbow, Senior Manager - Plant Health

Ms Jane O'Brien, Communication Manager

Animal Health Alliance (Australia) Ltd

Dr Peter Holdsworth AM FAICD, Chief Executive Officer

Dr David Chudleigh , Director, Regulatory, New Product Development and Scientific Affairs, Pfizer Animal Health

Dr John O'Brien, Managing Director, Jurox Pty Ltd