The Senate

Rural and Regional Affairs and Transport Legislation Committee

Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 [Provisions]

June 2014

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Recommendation

The committee recommends the bill be passed.

Chapter 1

Referral of inquiry

1.1 The Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (the bill) was introduced in the House of Representatives on 19 March 2014. On 20 March 2014, the Senate referred the provisions of the bill to the Senate Rural and Regional Affairs and Transport Legislation Committee (the committee) for inquiry and report by 16 June 2014.

1.2 The Selection of Bills Committee noted the reasons for referral and principal issues for consideration were to 'Investigate thoroughly the impact of this legislation on the health and safety of human beings, animals and the environment as a priority of the regulatory system.'[1]

Purpose of the bill

1.3 A key objective of the bill is to wind back the re-registration process for agricultural chemicals and veterinary medicines (together referred to as 'agvet chemicals').

1.4 In particular, the purpose of this bill is to:

- amend the *Agricultural and Veterinary Chemicals Code Act 1994* to:
  - prevent the expiry of active constituent approvals and prevent the application of dates after which a registration cannot be renewed;
  - remove the requirement for applications to be made to re-approve active constituents or re-register chemical products;
  - enable the Australian Pesticides and Veterinary Medicines Authority (APVMA) to require information to be provided about substances supplied as a chemical product;
  - simplify how variations to approvals and registrations are processed by APVMA; and
  - enable APVMA to charge a fee when it provides copies of documents in its possession; and
- amend the *Agricultural and Veterinary Chemicals Code Act 1994*, *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* and the *Food Standards Australia New Zealand Act 1991* to make consequential amendments.[2]

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1 Selection of Bills Committee, *Report no. 3 of 2014*, 20 March 2014, Appendix 1.

2 Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014, *Summary*, http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbillhome%2Fr5196%22, (accessed 14 April 2014).

Conduct of the inquiry

1.5 The committee wrote to a number of stakeholder groups seeking submissions on the provisions of the bill. Twenty two submissions were received. Given the non-controversial nature of the bill, the committee agreed not to hold a public hearing in relation to this inquiry.

Background

The regulatory environment

1.6 Agricultural chemicals and veterinary medicines are regulated through a cooperative National Registration Scheme (NRS) for Agricultural and Veterinary Chemicals. The NRS was first agreed to by the Australian Agriculture Council (subsequently the Standing Council on Primary Industries) in 1991 and is described in a ministerial level intergovernmental agreement that was signed in September 1995.[3]

1.7 The NRS is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities. Assessment and registration of agvet chemicals, as well as the control of supply activities up to the point of retail sale are undertaken on behalf of the states by the Australian Pesticides and Veterinary Medicines Authority (APVMA), a Commonwealth authority. Control of the use of agvet chemicals after sale is the responsibility of the states and territories.[4]

1.8 In 2006 an audit by the Australian National Audit Office (ANAO) examined the APVMA's arrangements for planning and overseeing the delivery of its regulatory functions and for administering its cost recovery framework.[5] The ANAO noted:

> Since the ANAO's previous audit in 1997–98, and particularly in recent years, the APVMA has introduced various initiatives to improve the effectiveness of its operations. However, key programs to monitor the quality of pesticides and veterinary medicines, such as the Manufacturers' Licensing Scheme and the Chemical Review Program, could be better administered. Greater emphasis needs to be given to compliance programs and to completing chemical reviews in order for the APVMA to provide assurance that manufacturers of pesticides and veterinary medicines are meeting the required standards, and that products approved for sale in Australia are safe and effective. 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.[6]

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3 Explanatory Memorandum, p. 4.

4 Explanatory Memorandum, p. 4.

5 Australian National Audit Office, *Regulation of pesticides and veterinary chemicals*, Audit report no. 14, 2006–07, December 2006, p. 14.

6 Australian National Audit Office, *Regulation of pesticides and veterinary chemicals*, Audit report no. 14, 2006–07, December 2006, p. 19.

1.9 In 2006, the Council for Australian Governments (COAG) identified the need for regulatory reform in relation to chemicals and established a Ministerial Taskforce, to 'develop a streamlined and harmonised national system of chemicals and plastics regulation'.[7] COAG also referred the matter to the Productivity Commission for advice. In 2008, the Commission published a report, *Chemicals and Plastics Regulation*, which found that:

> …the current institutional and regulatory arrangements are broadly effective in managing the risks to health and safety, but are less effective in managing risks to the environment and national security. Efficiency could be enhanced by: national uniformity in some regulatory areas; reducing costs and delays in obtaining regulatory approvals; and attaining economies of scale in regulatory administration.[8]

1.10 In 2009, COAG announced that a Memorandum of Understanding for Chemicals and Plastics Regulatory Reform had been agreed to, and established the Standing Committee on Chemicals to co-ordinate, monitor and advise governments on the implementation of reforms identified by the Productivity Commission.[9] In mid-2013 ministers confirmed their commitment to a new NRS agreement.[10]

1.11 The APVMA's operations are described in the Explanatory Memorandum as follows:

> The APVMA is responsible for administering and managing the parts of the NRS that oversee registration, quality assurance and compliance of agvet chemicals up to and including the point of retail sale.
>
> Australia currently has around 11 700 separate agvet chemical products registered (approximately 8 350 agricultural and 3 350 veterinary), each of which contains one or more of around 2 230 approved active constituents, of which around 782 are unique.[11]

Recent changes – the Amendment Act

1.12 The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013 (the amendment bill) was passed by Parliament in June 2013. The amendment bill made changes to: approvals, registrations, permits and licences, re-approval and re-registration, enforcement, data protection, and levy collection.[12] The amendment bill

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

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

9 Memorandum of Understanding for Chemicals and Plastics Regulatory Reform, Council of Australian Governments, www.coag.gov.au/node/93, (accessed 15 April 2014).

10 Explanatory Memorandum, p. 4.

11 Explanatory Memorandum, p. 4.

12 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, pp 2–8.

also included other amendments to remove redundant provisions and amend outdated provisions.[13]

1.13 Prior passing of the amendment bill, there was no mandatory requirement for agvet chemicals, once approved or registered, to be reviewed. Some of the amendments in the amendment bill provided for such a scheme as follows:

> The Act [as it became] reformed the approval, registration and reconsideration (review) of agvet chemicals to improve the effectiveness of the regulatory system and reduce inefficiency at the APVMA, while making processes more predictable, clearer and less unwieldy for industry. The reforms were intended to improve community's confidence that chemicals approved for use in Australia are safe.
>
> The reforms of the Amendment Act (including provisions for re-approval of active constituents and re-registration of chemical products, or re-registration) commence on 1 July 2014.[14]

1.14 The amendment bill was examined by four Parliamentary committees, including the Senate Standing Committee for the Scrutiny of Bills and the Parliamentary Joint Committee on Human Rights. The Senate Rural and Regional Affairs and Transport Legislation Committee tabled its report on 27 February 2013, recommending that the amendment bill be passed.[15] The Coalition Senators' Dissenting Report indicated that Coalition Senators did not support its passage on account of the mandatory requirement for re-registration of agricultural and veterinary chemicals, which was described as 'expensive and developed without a compelling cost/benefit analysis'.[16]

The bill

1.15 The Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (the bill) amends:

- the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act);
- the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act);
- the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act); and
- the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).[17]

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13 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, p. 2.

14 Explanatory Memorandum, pp 3–5.

15 *Journals of the Senate No. 135*, 27 February 2013, p. 3684; Rural and Regional Affairs and Transport Legislation Committee, *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 [Provisions]*, p. 26.

16 Rural and Regional Affairs and Transport Legislation Committee, *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 [Provisions]*, Dissenting Report, pp 27–30.

17 Explanatory Memorandum, p. 1.

1.16 The explanatory memorandum indicates that the bill implements an election commitment to remove the requirement to re-register agvet chemicals:

> The Bill implements the Australian Government's 2013 election commitment to remove the requirement for agricultural chemicals and veterinary medicines…re-registration by removing end dates for approvals and last renewal dates for registrations so that approvals will no longer end after a particular period and registrations may be renewed perpetually, and removing redundant provisions that allow applications to re-approve and re-register active constituents and chemical products.[18]
>
> The government considers that, prior to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*, existing chemical review mechanisms provided sufficient basis for the examination of newly discovered risks about the safety, efficacy or trade impact of a chemical. New mechanisms (the re-registration scheme) duplicating the existing system and impose additional costs on industry are not required. [19]

1.17 Schedule 1 of the Bill would amend the Agvet Code to prevent the expiry of active constituent approvals and prevent the application of dates after which a registration cannot be renewed. Active constituent approvals are to continue in force so long as they are not cancelled. Registrations would continue in force so long as they are not cancelled, subject to renewal of the registration. The bill would also remove provision for applications to be made to re-approve active constituents or re-register chemical products.[20]

1.18 While the bill would remove re-registration, other provisions strengthened by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* would be retained. The existing comprehensive powers held by APVMA ensure that any newly identified risks about the safety, efficacy or trade impact of a chemical are examined, would be retained. The APVMA would also retain powers to recall unsafe chemical products or suspend or cancel the registration of a chemical product if they no longer meet criteria for registration.[21] The bill would also introduce reforms that aim to:

- reduce red tape by providing for less frequent registration renewals;
- improve the APVMA's ability to secure information about the safety of chemicals supplied in the market;
- introduce further simple reforms to the regulation of agvet chemicals to reduce red tape and improve efficiency;
- oblige the APVMA to provide access to information about approvals and registrations in its files to persons eligible to receive it; and

18 Explanatory Memorandum, p. 1.

19 Explanatory Memorandum, p. 5.

20 Explanatory Memorandum, p. 10.

21 Explanatory Memorandum, p. 10.

- address some minor implementation issues identified in existing reform legislation.[22]

Consultation

1.19 A consultation paper and an exposure draft of the bill were released, with submissions sought between 18 December 2013 and 7 March 2014. The Explanatory Memorandum notes that 42 submissions were received and meetings were held with stakeholders over January and February 2014. The bill was revised to address some issues raised during the consultation.[23]

Acknowledgements

1.20 The committee thanks those organisations and individuals who made submissions.

22 Explanatory Memorandum, p. 1.

23 Explanatory Memorandum, p. 3.

Chapter 2

Issues

2.1 The majority of submitters to the inquiry supported the bill's main objective of removing the re-registration requirement for agricultural chemicals and veterinary medicines.[1] The bill would remove end dates for approvals and last renewal dates for registrations so that approvals no longer end after a particular period and registrations could be renewed perpetually.[2] In the main, submitters also supported other reforms introduced by the bill including:

- addressing concerns with chemical product quality;
- reducing red-tape by allowing for less frequent renewal of registration;
- reducing red-tape by allowing for simpler variations to approvals and registrations;
- facilitating access to information held by APVMA about chemicals; and
- other amendments consequential to existing reforms.[3]

2.2 The bill's primary objective, along with each of these other reforms, are discussed below.

Removing re-registration and re-approval

2.3 The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Amendment Act), discussed in the previous chapter, introduced the re-approval of active constituents and re-registration of chemical products by amending the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet code). Without changes to the Agvet Code, re-registration requirements will come into force on 1 July 2014, requiring periodic examination (every seven to 15 years) of active constituents and products.[4]

2.4 Schedule 1 of the bill would amend the Agvet Code to implement an election commitment to remove re-registration by:

- preventing the expiry of active constituent approvals and preventing the application of dates after which a registration cannot be renewed;

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1 Croplife Australia, *Submission 10,* p. 1; Plastics and Chemicals Industries Association, *Submission 7,* p. 2; Horticultural Industries Bodies, *Submission 8,* p. 4; NSW Farmers' Association, *Submission 16,* p. 3; Chestnut Australia Inc., Hazelnuts Growers of Australia Inc., Pistachio Growers' Association Inc., *Submission 18,* pp 4–5; Horticulture Coalition of SA Inc., *Submission 19,* p. 3; Animal Medicines Australia, *Submission 20,* p. 3; Australian Food and Grocery Council, *Submission 15,* p. 1.

2 Explanatory Memorandum, p. 1.

3 Explanatory Memorandum, pp 1–3.

4 Explanatory Memorandum, p. 1.

- removing provision for applications to be made to re-approve active constituents or re-register chemical products; and
- make additional consequential amendments to the Agvet Code, Collection Act and Amendment Act.[5]

2.5 Schedule 1 of the bill would also remove redundant provisions for applications to re-approve and re-register active constituents and chemical products. Consequential amendments would also be made to the Agvet Code, the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.[6]

2.6 The majority of submitters support the removal of re-approval and re-registration.[7] The Queensland Department of Agriculture, Fisheries and Forestry submitted that 'at a practical level, it is considered that the re-registration and re-approval scheme was unlikely to have achieved its aim so the amendment to remove references to re-approval and re-registration in the legislation is supported.'[8] The Australian Forest Products Association submitted that: 'The bill details some positive reforms that will improve the existing regulation and regulatory bodies, and create more certainty for all stages of the agvet assessment and registration process.'[9]

2.7 Issues raised by submitters in relation to re-approval and re-registration include: impacts on industry and the APVMA; risk-based versus systematic assessment; protection of consumers and the environment; and avoiding the loss of generic and other products.

Impact on industry and the APVMA

2.8 In its submission the Department of Agriculture noted that without changes to the Agvet Code, the re-registration requirements due to come into force on 1 July 2014 would lead to significant costs to both industry and the APVMA:

> Unless removed, the re-registration scheme is expected to increase the APVMA's costs by $2.2 million per year once the initial roll-out of the scheme is complete.

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5 Explanatory Memorandum, p. 2.

6 Department of Agriculture, *Submission 22*, p. 6.

7 Queensland Department of Agriculture, Fisheries and Forestry, *Submission 5*, p. 2; Australian Dairy Farmers, *Submission 6*, p. 1; Croplife Australia, *Submission 10*, p. 5; Plastics and Chemicals Industries Association, *Submission 7*, p. 2; Horticultural Industries Bodies, *Submission 8*, p. 4; NSW Farmers' Association, *Submission 16*, pp 4, 7; Chestnut Australia Inc., Hazelnuts Growers of Australia Inc., Pistachio Growers' Association Inc., *Submission 18*, pp 3–4; Horticulture Coalition of SA Inc., *Submission 19*, p. 3; Animal Medicines Australia, *Submission 20*, p. 1.

8 Queensland Department of Agriculture, Fisheries and Forestry, *Submission 5*, p. 2.

9 Australian Forest Products Association, *Submission 11*, p. 4.

> The Australian Bureau of Agricultural and Research Economics and Sciences (ABARES) estimates total business costs would be $324,000 per year in preparing applications for re-approval or re-registration.[10]

2.9 The potential costs of the re-approval and re-registration were also estimated by Croplife Australia, including direct costs to industry as well as the opportunity costs of supporting existing registrations, as opposed to innovating and developing new products:

> Based on analysis conducted by CropLife Australia in 2011, direct costs to registrants are conservatively expected to be at least $6.75 million per annum, representing an approximate increase of 25 per cent in total cost recovered fees imposed on registrants. A more likely outcome would be in excess of $10 million per annum.
>
> The opportunity costs from registrants supporting existing registrations rather than innovating, developing and registering new, safer and softer agricultural chemical products will be significant.[11]

2.10 Other disadvantages of the retention of the re-approval and re-registration process include the extra time taken to complete a re-registration, and the uncertainty and burden to industry.[12] CropLife Australia submitted that re-registration and re-approval would add additional bureaucracy and inefficiency which would likely result in reduced capacity within the APVMA to deliver timely, high quality chemical reviews.[13] The Australian Forest Products Association (AFPA) indicated that:

> The mandatory re-approval and re-registration provisions were unnecessary and did not meet the often stated objective to '*increase the scrutiny of chemical constituents and products through a scheme that minimises impacts on industry'*. The additional regulatory processes were likely to increase costs and uncertainty for industry, making it very difficult to maintain the existing suite of chemicals and minor uses**.**[14]

2.11 The committee considers that removing re-registration and re-approval is likely to reduce costs and other negative impacts on industry and the APVMA.

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10 Department of Agriculture, *Submission 22*, pp 6–7.

11 CropLife Australia, *Submission 10*, p. 4.

12 Australian Forest Products Association, *Submission 11*, p. 2; Australian Dairy Farmers, *Submission 6*, p. 1; Plastics and Chemicals Industries Association, *Submission 7*, p. 2.

13 CropLife Australia, *Submission 10*, p. 5.

14 Australian Forest Products Association, *Submission 11*, p. 3.

Risk-based approach

2.12 Submitters supported a return to a risk-based approach to regulation that would result from the removal of re-registration and re-approval.[15] The Plastics and Chemicals Industries Association (PACIA) noted that the re-approval and re-registration scheme was intended to be risk-based, however 'by failing to identify areas of risk being targeted has resulted in a scheme that is not targeted at risk, in contrast to the rest of the regulatory scheme.'[16] The Horticultural Industries Bodies also raised concerns that the Amendment Act moved away from a risk-based approach:

> Horticultural industries recognize that an important element of the regulatory framework is the reassessment of older chemicals against contemporary standards. Nevertheless, industries were extremely concerned that the approach taken in the legislation signified a more prescriptive regulatory approach which appeared to be moving away from current risk-based assessments with the potential to adversely impact on agvet chemical access.[17]

2.13 Croplife Australia also supported a risk-based approach, on the basis that it would focus the APVMA's resources where they are needed, rather than spreading the resources too thinly.[18] In addition, Grain Producers Australia supported the bill, noting the difference between the European hazard-based approach and the risk-based approach used in Australia.

> The proposed removal of Schedule 2 – 47A relating to varying duration—decisions of foreign regulators is supported by GPA. This section would have potentially forced the APVMA to consider a large number of such compounds upon the implementation of the EU hazard-based regulatory scheme, i.e., where use of a compound with dual applications may be prohibited in the EU on the basis of hazard-based policy rather than risk as considered in Australia.

2.14 The committee considers that the bill would return the assessment of agvet chemicals to a risk-based approach, and notes that this is supported by industry.

Protection of consumers and the environment

2.15 Some submitters raised concerns that the bill could see a reduction in the level of protection for consumers and the environment from risks associated with pesticides

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15 Croplife Australia, *Submission 10*, p. 3; Plastics and Chemicals Industries Association, *Submission 7*, p. 2; Horticultural Industries Bodies, *Submission 8*, p. 2; NSW Farmers' Association, *Submission 16*, p. 4; Chestnut Australia Inc., Hazelnuts Growers of Australia Inc., Pistachio Growers' Association Inc., *Submission 18*, p. 3; Horticulture Coalition of SA Inc., *Submission 19*, p. 1; Animal Medicines Australia, *Submission 20*, p. 1.

16 Plastics and Chemicals Industries Association, *Submission 7*, p. 2.

17 Horticultural Industries Bodies, *Submission 8*, p. 2.

18 Croplife Australia, *Submission 10*, p. 3.

and products.[19] However, the Department of Agriculture advised that sufficient protections are in place to ensure health and safety, noting the comprehensive powers of the APVMA, strong systems to trigger chemical reviews and powers to recall or suspend unsafe products:

> …[the bill] will retain the existing comprehensive powers the APVMA has that ensure any newly identified risks about the use of a chemical on human, animal and environmental safety, to efficacy or to trade are examined.
>
> …A reconsideration may be triggered if previously unknown potential risks to safety, efficacy or trade have been reported or if the APVMA discovers evidence that shows a product may be unsafe…
>
> The APVMA also retains powers to recall unsafe chemical products if the product may not meet the contemporary safety, efficacy or trade criteria for registration, or to stop sale of the product.
>
> The APVMA may also suspend or cancel the registration of a chemical product or approval of an active constituent if it no longer meets the stringent criteria for registration. After 1 July 2014 the APVMA will also be able to suspend or cancel an approval or registration to prevent imminent risk to persons of death, serious injury or serious illness.[20]

Avoiding the loss of products to the market

2.16 Several submitters noted that one of the benefits of removing the re-registration and re-approval is that it will avoid the loss to the market of many established treatments and products that would have otherwise occurred under the existing legislation.[21] The Horticultural Industries Bodies submitted that:

> The allocation of resources would also have been the scenario facing horticultural industries wishing to support continued access to any agvet chemicals under reassessment, i.e., industry funding to support nominated compounds could not be provided in the requisite timeframes. The unforseen outcome of which would have been the loss of access to many needed agvet chemicals, irrespective of any identified concerns, thereby, reducing available pest, disease and weed management options.[22]

2.17 Grain Producers Australia raised similar concerns about the loss of generic products under the existing legislation and welcomed the changes in the bill, including returning to a scientifically sound registration process:

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19 Choice, *Submission 21,* p. 4; WWF-Australia and National Toxics Network, *Submission 9,* p. 1.

20 Department of Agriculture, *Submission 22,* p. 7.

21 Australian Dairy Farmers, *Submission 7,* p. 1; CropLife Australia, *Submission 10,* pp 2, 7; Chestnut Australia Inc., Hazelnuts Growers of Australia Inc., Pistachio Growers' Association Inc., *Submission 18,* p. 4; Horticultural Coalition of SA Inc., *Submission 19,* p. 3; Grain Producers Australia; *Submission 13,* pp 2, 3.

22 Horticultural Industries Bodies, *Submission 8,* p. 3.

> It is important that APVMA reviews are based on science-based evidence where adverse events or new international scientific evidence calls for reconsideration of existing chemical actives. The Australian grains industry is not resourced to meet the potential significant cost of an unnecessary regulatory process where time bound compulsory re-registration is likely to result in commercial market failure for regulatory support of generic off patent chemical actives. The repeal of the Schedule 1 compulsory re-registration process is a scientifically sound and appropriate decision for the government.[23]

2.18 The NSW Farmers' Association consider that the changes proposed in the bill would provide better incentives for the research and development of safer chemical products:

> During consultation over the 2013 amending bill, the major registrants of new and novel agricultural chemical technologies outlined that the costs of compliance with the reregistration/re-approval scheme would actually result in a perverse outcome in which less money within their R&D budgets would be allocated to the bringing of newer, novel and potentially safer chemical products to market. The repeal of the uncommenced scheme is an important part of providing a stable and effective regulatory regime that will provide the incentives for these newer technologies to be brought to Australia sooner for the benefit of agricultural productivity and profitability, and to provide tools to better manage environmental pests and disease.[24]

2.19 The committee notes that the changes proposed in the bill are designed to avoid the loss of products that could have occurred under the existing legislation.

Addressing concerns with chemical product quality

2.20 There are concerns that chemicals that have been imported for which the contents of the product are not consistent with its label, or that it is a danger to health because of impurities in the product.[25] The committee heard that removing re-registration would also remove an opportunity for the APVMA to confirm that chemical products supplied to the market are the same as the product evaluated and registered by the APVMA.[26]

2.21 Schedule 2 of the bill addresses this issue by amending section 99 of the Agvet Code to improve the ability of the APVMA to require a person who supplies an agvet chemical product in Australia to provide information about the product they are supplying. The information that may be required includes:

- the constituents of the substance or mixture;
- the concentration of the constituents of the substance or mixture;

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23 Grain Producers Australia, *Submission 13,* pp 2, 3.

24 NSW Farmers' Association, *Submission 16,* p. 7.

25 Department of Agriculture, *Submission 22,* p. 7.

26 Explanatory Memorandum, p. 2.

- the formulation type of the substance or mixture;
- the composition or purity of a constituent of the substance or mixture;
- the name of each manufacturer of the substance or mixture;
- the address of each site at which the substance or mixture is manufactured;
- the packaging or labelling of the substance or mixture;
- advertising material related to the substance or mixture;
- whether substances mixtures conform to standards; and
- any other prescribed information or documents.[27]

2.22 Submitters largely supported the chemical product quality changes proposed in the bill.[28] CropLife Australia considered that improving the capacity for the APVMA to secure information about the safety of chemicals supplied in the market would provide a meaningful improvement in human health, safety or environmental protection. CropLife supported the APVMA having all necessary powers to properly manage the agricultural chemical portfolio.[29]

2.23 Choice submitted that it would prefer chemical product quality information to be gathered systematically.[30] Other submitters considered limits on APVMA's information gathering powers to be important. For example, the Australian Forest Products Association advocated that safeguards should be put in place to prevent the APVMA from requiring information unless it believes it is reasonably necessary to do so:

> AFPA understands the Government's policy objective for the APVMA to improve its ability to secure information about the safety of chemicals supplied in the market. AFPA urges that any reform in this area be scientifically based, targeted at areas of concern, and aligned with the principles of assessment for 'risk' rather than 'hazard'. AFPA supports the implementation of an effective and practical safeguard system to be applied to the APVMA in relation to this issue. The safeguard system would prevent the APVMA from requiring information unless it believes it is reasonably necessary to protect human, animal, plant or environmental health or safety, or implications on trade.[31]

2.24 The NSW Farmers' Association supported the changes on chemical product quality and noted in its submission that reasonable restraints would be retained upon

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27 Department of Agriculture, *Submission 22*, p. 8.

28 Plastics and Chemicals Industries Association, *Submission 7*, p. 3; CropLife Australia, *Submission 10*, p. 6; Agforce Queensland, *Submission 14*, p. 5; NSW Farmers' Association, *Submission 16*, p. 8.

29 CropLife Australia, *Submission 10*, p. 6.

30 Choice, *Submission 21*, p. 18.

31 Australian Forest Products Association, *Submission 11*, p. 3.

APVMA's power, including that the APVMA 'must hold a reasonable suspicion prior to exercising the power.'[32]

Reducing red-tape by allowing for less frequent renewal of registration

2.25 The APVMA currently keeps product and company details up to date through an annual renewal of registration. The associated fees recover some of the ongoing costs of regulating agvet chemical products available on the market. The bill would reduce red tape by providing for less frequent renewal of registration. The renewal period would be set in regulations, and would be aimed at balancing flexibility for industry against the cost of administration.[33]

2.26 Measures to allow less frequent renewal of registrations, including flexible renewal options, were popular.[34] The NSW Farmers' Association suggested that the development of options for renewal periods should be undertaken in consultation with peak bodies.[35] Croplife Australia emphasised the importance of a flexible approach for chemicals that have short and long commercial uses:

> Due to different chemical products having differing commercial drivers, there is a need to have both annual and multiple year renewal of registration options. There will always be the case where products are intended to be superseded in the short to medium term. By only having multiple year renewal periods available, refunds of renewal fees or unacceptable renewal fees for products with a limited future would be required. Therefore, to encourage innovation by allowing for the flexible management of chemical product renewals, both annual and multiple year renewal of registration options are required.[36]

2.27 It was also noted that consideration of any changes arising from the review of APVMA's costs recovery arrangements will be important.[37]

2.28 The committee notes that less frequent renewal of registration is likely to reduce red-tape and improve efficiency for industry and the APVMA.

Reducing red-tape by allowing for simpler variations to approvals and registrations

2.29 The bill would amend Division 2A of Part 2 of the Agvet Code Act and insert a new Division 2AA designed to improve the effectiveness of the Agvet Code and

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32 NSW Farmers' Association, *Submission 16,* p. 8.

33 Department of Agriculture, *Submission 22,* p. 8.

34 Plastics and Chemicals Industries Association, *Submission 7,* p. 3; Croplife Australia, *Submission 10,* p. 5; Australian Forest Products Association, *Submission 11,* p. 2; Australian Food and Grocery Council, *Submission 15,* p. 1; NSW Farmers' Association, *Submission 16,* p. 8.

35 NSW Farmers' Association, *Submission 16,* p. 8.

36 Croplife Australia, *Submission 10,* p. 5.

37 Choice, *Submission 21,* p. 17.

increase efficiency in dealing with variations of approvals and registrations.[38] The explanatory memorandum argues that:

> These simplified application processes will greatly reduce the supporting information required and industry time taken to make a variation to a registration or approval. Without these amendments to the Agvet Code, the APVMA would have to complete a more onerous technical assessment of these variations with no real benefit to improving chemical safety.[39]

2.30 The Department of Agriculture submitted that the new provisions would allow for a streamlined application process for simple variations which would be set out in regulations. The new process would avoid more onerous technical assessments. A variation would only be able to be made under these simplified provisions if the chemical product still meets safety, trade and efficacy assessment criteria.[40] The following variations were identified through consultation with industry as being candidates for the simplified process :

- changes to a product's name, perhaps because the supplier company changes hands, or to respond to market demand;
- introducing smaller pack sizes where larger versions already exist;
- specialising products by focussing on particular use patterns for a product with a specialised name;
- changing sites of manufacture to respond to changes in the company's supply chain;
- minor variations to chemical composition resulting from improved ingredient quality, to respond to changes in the company's supply chain or to respond to market demand – for example, to change the scent of a personal insect repellent or change the colour of a flea collar.[41]

2.31 PACIA promoted the need to facilitate minor variations arising from minor specification changes, such as might result from changes to manufacturing processes, where there is no impact on product quality or safety.[42] Nonetheless, it was also noted that formulation changes can significantly impact the toxicity of the products and that this area may need further attention by the APVMA.[43]

2.32 Some submitters suggested additional consultation (including with peak bodies) will be needed on the legislative instrument to implement the changes:

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38 Explanatory Memorandum, pp 2, 22.

39 Explanatory Memorandum, p. 2.

40 Department of Agriculture, *Submission 22*, p. 9.

41 Department of Agriculture, *Submission 22*, p. 9.

42 Plastics and Chemicals Industries Association, *Submission 7*, p. 3.

43 WWF-Australia and National Toxics Network, *Submission 9*, p. 11; Choice, *Submission 21*, pp 19–20.

> While the content of the legislative instrument to be made under section 26A would need to be subject to additional consultation to ensure that it encompasses the greatest range of potential variations possible without undermining product safety, PACIA supports this initiative as an important component that, coupled with appropriately targeted compliance activities, can successfully and efficiently address concerns about products supplied to the Australian market. [44]

2.33 Animal Medicines Australia strongly supported the changes for simpler variations, and emphasised the importance of future regulations containing a defined set of circumstances for minor variations to be determined through further consultation:

> What is required to achieve greater simplicity in this area of regulation is a clearly defined set of circumstances in which minor variations may be rendered more or less self-executing by way of notification to APVMA. Animal Medicines Australia is encouraged by initial consultation on this matter with the Department of Agriculture, and is eager to continue to work with the Department and APVMA to make improvements in this area.[45]

2.34 The committee notes that the changes effected by the bill are likely to make it easier for industry and the APVMA to keep product information up to date.

Facilitating access to information held by APVMA about chemicals

2.35 The APVMA is often asked by companies to provide information relating to registered chemical products, such as the formulation and manufacturing details provided in a registration application. The companies may not have retained the information, or may not have received it when they acquired an interest in the product. While the APVMA provides information under the *Freedom of Information Act 1982* (FOI Act), the fees charged do not cover the costs of providing the information.[46] The Department of Agriculture submission indicates that:

> The Bill will 'turn off' access under the FOI Act but will provide for persons to apply to the APVMA for copies of documents it holds about a chemical (of that company) for a fee.[47]

2.36 PACIA acknowledged the challenges facing both the APVMA and industry in maintaining information on chemical products:

> As some products have very long product lifespans, they may exist through a number of commercial restructures, divestments and mergers. From time to time this may mean that a company is not fully aware of the information that the APVMA holds in relation to its registered products. This places

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44 Plastics and Chemicals Industries Association, *Submission 7*, p. 3; see also NSW Farmers' Association, *Submission 16*, p. 9.

45 Animal Medicines Australia, *Submission 20*, p. 2.

46 Department of Agriculture, *Submission 22*, pp 9–10.

47 Department of Agriculture, *Submission 22*, p. 10.

> particular challenges on the APVMA's compliance activities and on registrants' responsibility to manage their product portfolio.[48]

2.37 Submitters were comfortable moving to a more efficient mechanism than FOI for accessing product information, as long as the mechanism was of low cost to industry.[49] PACIA welcomed further consultation on the fees that would be set.[50] While some concerns were raised about the impact of the proposed changes, the Department of Agriculture concluded that 'These amendments do not reduce or limit access to information to persons eligible to receive it. Access remains subject to commercial-in-confidence considerations, protecting the commercial property of companies.'[51]

2.38 On balance, the committee considers that the proposed changes are likely to be advantageous to the APVMA and industry, and adequate safeguards remain in place to facilitate appropriate access to relevant information.

Other amendments consequential to existing reforms

2.39 The explanatory memorandum notes that the bill seeks to correct some technical issues with the Amendment Act to the Agvet Code and the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

> the Amendment Act inadvertently undid 2010 amendments to the FSANZ Act. The 2010 amendments were an efficiency measure to allow the APVMA to amend the Maximum Residue Limit Standard of the Australia New Zealand Food Standards Code. The FSANZ Act will be amended to correct an incorrect reference to part of the Agvet Code in the FSANZ Act. Schedule 2 of the Bill addresses these amendments.
>
> …several minor technical amendments are required to the Agvet Code to improve the readability of the legislation and reduce the possibility of difficulties in implementing it. Schedules 1 and 2 of the Bill address these miscellaneous amendments as appropriate.[52]

2.40 Choice suggested that more explanation of the consequences of the amendments could be provided.[53] WWF-Australia and the National Toxics Network had no problem with the consequential amendments if they are genuinely minor in nature and do not diminish human health and environmental protections.[54] PACIA

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48 Plastics and Chemicals Industries Association, *Submission 7*, p. 4.

49 Australian Forest Products Association, *Submission 11*, p. 4; Plastics and Chemicals Industries Association, *Submission 7*, p. 4; Australian Food and Grocery Council, *Submission 15*, p. 1.

50 Plastics and Chemicals Industries Association, *Submission 7*, p. 4.

51 Department of Agriculture, *Submission 22*, p. 10. WWF-Australia and National Toxics Network, *Submission 9*, p. 12; Choice, *Submission 21*, p. 22.

52 Explanatory Memorandum, p. 3.

53 Choice, *Submission 21*, pp 22–23.

54 WWF-Australia and National Toxics Network, *Submission 9*, p. 13.

supported the consequential amendments, including the reinstatement of the FSANZ Maximum Residue Limit standard.[55]

Committee view

2.41 The committee has considered the bill and notes that the majority of submitters support its passage. In particular, the committee considers that the bill would improve the administration of the agvet regime by returning to a risk-based approach to chemical assessment, approval and registration, and that that is likely to provide efficiencies to both industry and the APVMA.

Recommendation

The committee recommends the bill be passed.

Senator the Hon Bill Heffernan

Chair

55 Plastics and Chemicals Industries Association, *Submission 7*, p. 4.

Dissenting report – Australian Greens

1.1 The Australian Pesticides and Veterinary Medicines Authority (APVMA) has only just gained the legislative triggers it needs to systematically review and quickly remove highly hazardous and unmanageable pesticides from the market if they fail to meet today's scientific and regulatory standards, making way for safer, greener pesticides.

1.2 It is extremely disappointing that these important and long overdue amendments due to come into effect in July are being unwound. The re-approval and re-registration scheme would ensure Australia finally undertook a systematic review of its ag-vet chemical inventory, many of which have never been subject to contemporary risk assessment and are not considered safe by any modern measure, yet persist in our community.

1.3 Legislated risk-based re-registration schemes operate in the USA, Canada and the European Union. The key focus of re-registration in these jurisdictions is to ensure older pesticides on the market are subjected to the same standards applied to pesticides registered today.

1.4 Australia has a problem and the re-registration scheme is designed to fix it. Australia has hundreds of pesticides that were 'grandfathered' into the National Registration Scheme that have never been risk assessed. These products are sold and used today and the risks they pose to the community, the environment and trade have never been quantified and the risk management strategies needed to control their negative impacts have not been specified.

1.5 Without re-registration, the APVMA will continue to operate in much the same way it always has with respect to chemical reviews and the fundamental problem of inadequately assessed pesticides remaining on the market will not be systematically addressed.

1.6 The APVMA has a poor track record with its chemical review program with many high risk pesticides under review for 10-15 years without adequate action being taken to mitigate risks, or indeed remove pesticides from use that are clearly just too dangerous.

1.7 Without a re-registration scheme, the APVMA has only an ad hoc approach to chemical review. There is no rationale in what ends up on the chemical review list and no guarantee that regulatory effort will be focused in on the pesticides of greatest risk.

1.8 According to the submission to the Senate Rural and Regional Affairs and Transport Legislation Committee Inquiry by the Queensland Government (the control of use regulator):

> The general concept of re-registration and re-approval has merit and is utilised by many overseas regulators as a way of ensuring that agvet chemicals have been approved by modern risk assessment principles. In Australia, there are a large number of uses if agvet chemical products that

> were approved by the registration system of the States and Territories, prior to the formation of the APVMA that have not been reassessed by modern risk assessment principles.
>
> One of the great promises of national registration was that the 'grandfathered' products would be re-assessed. There has been limited progress in re-assessing the uses of these products under the APVMA Chemical Review program."

1.9 The re-approval and re-registration scheme does not undermine a risk-based regulatory scheme - it enhances it. The current situation saw hundreds of products permitted to be on the market without ever having been risk-assessed to contemporary standards, and they're not likely to be under the Governments proposed ad hoc approach, this isn't a rigorous science-based risk assessment scheme; it's hit and miss regulation.

1.10 The re-registration scheme is based on scientific information and designed to make sure full chemical risk assessment reviews are done on the most high-risk products. In the first instance, the re-registration scheme sorts chemicals based on high, medium or low risk with hazard criteria helping to inform this sorting process. For instance, if a pesticide causes cancer and bioaccumulates in our bodies and the environment, then it should go to the top of the list as a high priority.

1.11 Once sorted, the regulator determines whether they are satisfied based on the science before it for that the product can continue to be used safely, or whether it needs to conduct a full risk-assessment to ensure the product can continue or not. If there are no concerns and current risk management statements are adequate, then the pesticide doesn't undergo full risk-assessment.

1.12 There's been a lot of discussion about hazard versus risk during this inquiry and these are terms that need to be understood in the context of chemical regulation. A risk assessment is a 'science-based tool' while 'a hazard-based approach takes away the scientific rigour of risk assessments.' The Australian Greens support the retention of the risk based framework, however we do not agree with the assertions that last year's reforms undermined this framework.

1.13 Re-regulation is still a risk-based process, even though it is initially informed by hazard assessment. Nor are the initial hazard assessments fundamentally different to risk assessments in this context. They are still based on the same toxicological and epidemiological research as risk assessment (obviously, since risk assessment is the next step after hazard assessment).

1.14 Risk assessment uses an extra set of data (exposure scenarios) but whether or not that makes it 'more science-based' must surely depend on the quality of the science behind the extra data. An extra volume of data does not necessarily improve the management of risk from a chemical; risk can still be underestimated because an absence of data or because the impact of an exposure to that chemical is simply too complex to model.

1.15 This is why in some circumstances a line needs to be drawn in the sand, even within a risk-based system. There are some pesticides that simply cannot be risk-

managed and this must be acknowledged. The global direction is to move away from highly hazardous pesticides towards safer ones and Australia shouldn't be left behind.

1.16 As new evidence emerges about the possibility of low-dose effects, cumulative toxicity of mixtures, endocrine disruption and so forth – all new developments unanticipated by risk assessment practices in the past, the Regulator needs a process in place to respond to the information.

1.17 If re-registration were to be repealed, we would return to the status quo whereby the Regulator would be reliant on an ad hoc chemical review program to address the problem of the hundreds of pesticides 'grandfathered' onto the National Registration Scheme that have not been adequately risk-assessed.

1.18 While comparable jurisdictions like the USA and Canada move ahead with legislated re-registration programs to ensure the ongoing safety of their pesticide inventories, Australia will continue to lag behind, putting its farmers, consumers, environment and trade at risk.

1.19 The science of toxicology is undergoing a revolution with the recognition of unintended impacts of pesticide exposure on our health and the environment. The role that environmental pesticide exposures might play in the development of certain cancers, Parkinson's disease and metabolic disorders for instance is currently subject to a great deal of scientific scrutiny.

1.20 Leaving the APVMA without a systematic mechanism to bring products back before it for assessment is asking them to regulate with one hand tied behind their backs. Science is always changing and throwing up new concerns, community expectations are changing and farmers need the safest tools to use.

1.21 The Australian Greens support the retention of the re-registration program. However, if re-registration is removed from the Act, then including criteria that will ensure high priority pesticides are identified quickly and –re-assessed is vital. The Greens recommend that the triggers outlined in the letter from then Minister for Agriculture Senator Ludwig, tabled as part of the debate on the APVMA Amendments last year and included as an appendix to these comments, be incorporated into the APVMA Act itself rather than left in regulation.

1.22 These included:

1. On toxicity to humans and wildlife:
    - chemicals in Schedule 7 of the Poisons Standard, that is, dangerous poisons with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use;
2. On bioaccumulation, about chemicals that accumulate in fatty tissues:
    - chemicals with a recognised bioconcentration factor of greater than 500, or with an octanol/water partition coefficient of greater than 4;
3. On degradation and persistence, chemicals that remain intact for exceptionally long periods of time:

- chemicals that do not rapidly degrade (assessed using OECD test guidelines 301 or 306) or chemicals with a half-life in water greater than two months or in soil or sediment greater than six months;
- the absence of rapid degradation in the environment can mean that the substance in water can exert toxicity over a wide temporal and spatial scale;

4. On long range transport, potential for wide distribution throughout the environment:
    - chemicals that don't rapidly degrade and which may be used in circumstances that can lead to transport beyond the target use site, chemicals measured at levels of concern in locations distant from release.

1.23 These criteria can be satisfied by prescribing all substances that are classified as chronic Category 1 under the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and that are included in Schedule 7 of the Poisons Standard maintained by the Department of Health and Ageing. The letter notes that DAFF's initial assessment was that there are around 42 substances that would meet these criteria.

1.24 Furthermore, one or more comparable jurisdictions having banned or severely restricted a pesticide should also be incorporated as triggering a review by the APVMA, if re-registration is repealed.

1.25 In conclusion, The Australian Greens believe that unwinding the re-registration scheme will re-introduce the assumption that a pesticide is 'innocent' of any negative impacts until it's proven 'guilty', beyond a doubt that damage is occurring from it. This benefits chemical corporations, not the people or the environment. It is well overdue for Australia to develop a systematic approach to removing previously untested chemicals from the market. The re-registration scheme remains the most rigorous, cost-effective and efficient approach to achieving that outcome.

1.26 For these reasons, the Australian Greens recommend that this Bill not be passed.

Senator Rachel Siewert
Australian Greens Senator for Western Australia

Appendix 1

Submissions received

Submission Number	Submitter
1	CANEGROWERS
2	National Farmers' Federation
3	Accord
4	Pastoralists and Graziers Association of Western Australia
5	Queensland Department of Agriculture, Fisheries and Forestry
6	Australian Dairy Farmers
7	Plastics and Chemicals Industries Association
8	Horticultural Industries Bodies
9	WWF-Australia and the National Toxics Network
10	CropLife Australia
11	Australian Forest Products Association
12	International Animal Health
13	Grain Producers Australia
14	AgForce Queensland
15	Australian Food and Grocery Council
16	NSW Farmers
17	Tasmanian Agricultural Productivity Group
18	Chestnuts Australia, Hazelnut Growers of Australia and Pistachio Growers' Association
19	Horticulture Coalition of SA
20	Animal Medicines Australia
21	CHOICE
22	Department of Agriculture