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.
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> 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.
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> …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.