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.