



**Submission in response to the Revised Exposure Draft of the
Agricultural and Veterinary Chemicals Legislation Amendments
Bill 2012**

October 2012

**NSW Farmers' Association
Level 25, 66 Goulburn Street
Sydney NSW 2000**

NSW Farmers' Association Background

The NSW Farmers' Association (the Association) is Australia's largest State farmer organisation representing the interests of its farmer members – ranging from broad acre, livestock, wool and grain producers, to more specialised producers in the horticulture, dairy, egg, poultry, pork, oyster and goat industries.

Executive Summary

NSW Farmers welcomes the opportunity to continue its involvement in the reform of Agvet policy in Australia by providing comment to the Department of Agriculture, Fisheries and Forestry on the revised exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill). We have also previously provided comment on the development of the Better Regulation of Agvet Chemicals Reform and on the process to develop a national scheme for assessment, registration and control of use of Agvet chemicals.

In this submission, NSW Farmers:

- Outlines continued concern that a thorough benefit cost analysis of the reforms, most particularly the re-registration scheme, has not been undertaken.

Risk Based

- Re-affirms industry's support for a risk based approvals process, including statutory support for the development of risk management guidelines for the APVMA to follow in its approval processes. The submission calls for the removal of the APVMA's discretion in developing these risk management guidelines.
- Seeks the implementation of a net benefit, or systems based approach to the risk management processes utilised by the APVMA in the approval process. This will examine the net benefits of a proposed approval, including impacts of pests, alternative chemicals and impacts of pest resistance to chemicals, in considering an application.
- Opposes the proposed re-registration system, on the basis that the risk management approach of the Chemical Review system is a better way to prioritise the resources of the APVMA and industry to ensuring chemicals used for Australian agriculture remain safe.
- Opposes the use of foreign regulatory decisions *per se*.

Minor Use Industry Concerns

- Supports mechanisms that will assist minor use industries, such as the provision enabling new uses to be added to the registration of an Agvet product by industry bodies with the consent of the registrant.
- Supports approaches that genuinely streamline the approvals process without hindering the provision of access to chemical products to farmers. As such NSW Farmers does not support the grounds for mandatory refusal within the Bill, nor the limitation of the information to be considered. NSW Farmers recommends:
 - the tempering of mandatory refusal by a consideration of whether it is more efficient to amend the application; and
 - a process that enables new information that would assist the APVMA meet its charter of a being a 'structured and scientific, evidenced based'

independent evaluator of chemicals, to be considered on a case by case basis.

- Opposes provisions that place the suitability of the capacity of industry groups to hold minor use permits at risk through unintended consequences of the proposed disqualifying criteria.

TABLE OF CONTENTS

Introduction	5
General Comments	6
Consultation Process	6
Benefit Cost Analysis	6
Schedule 1 – Approval Processes	7
Statutory Objectives and Guidance on Implementation	7
Safety, Trade, Efficacy, Labelling Criteria	8
Risk Based Framework	9
Streamlined Approval Process	10
Limitations on Information	11
Varying particulars and conditions	12
Chemical Reconsideration	12
Holders of Permits	13
Use of International Data and Regulatory Decisions	14
Schedule 2 – Re-Registration Framework	16
General Comments	16
Re-approval or Re-registration	17
Schedule 3 – Enforcement	19
Schedule 4 – Data Protection	19

Introduction

NSW Farmers is Australia's largest state farming organisation representing the interests of the majority of commercial farm operations throughout the farming community in NSW. Through its commercial, policy and apolitical lobbying activities it provides a powerful and positive link between farmers, the Government and the general public.

NSW Farmers welcomes the opportunity to provide comment to the Department of Agriculture, Fisheries and Forestry on the revised exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill). We have also previously provided comment on the first exposure draft of the Bill (Initial Bill) in February 2012, the 'Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper' (the Discussion Paper) published in November 2010 (2010 Paper), and participated in the process to develop a national scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals.

Whilst NSW Farmers is supportive of reforms which will increase the efficiency and effectiveness of the Australian Pesticides and Veterinary Medicines Authority (APVMA) and enable more effective regulation of agricultural and veterinary chemicals (Agvet chemicals), we are not convinced that the measures within the Bill achieve this goal. This submission will seek to outline key concerns that NSW Farmers has identified with the legislative amendments contained in the Bill.

Australia is a relatively small component of the global market for Agvet chemicals. For crop protection chemicals alone, the Australian market accounts for one sixth of the value of USA sales, and one tenth of sales made in Europe.¹ As such, any costs and impediments associated with the Australian regulatory framework for access to Agvet chemicals, may result in delays and withholding of product from the Australian market. This detracts from the productivity and profitability of Australia's farmers.

NSW Farmers has determined industry policy with regard to the need of end users in the agricultural and veterinary chemical registration scheme. These needs include a system which:

- is underpinned by sound evidence-based science;
- encourages the registration of new products and increases the suite of chemistry available, particularly those that are suitable for integrated pest management (IPM) systems and are already available to international competitors;
- enables an efficient minor use permit system and improves access to chemicals by small agricultural industries;
- ensures chemicals that are safe and effective remain available;
- ensures farmers have sufficient chemistry available to allow chemical rotations and implementation of resistance management strategies;
- minimises the cost of regulation and compliance that may be passed onto Agvet chemical users; and

¹ Deloitte Access Economics (2012) 'Review of APVMA Cost Recovery Discussion Paper', 13.

- considers the impact of approvals and regulatory decisions on agricultural chemicals upon the whole farming and environmental system. This includes the opportunity cost impacts of alternative controls, failure to control the target pest, and the impact upon resistance management.

Additionally, NSW Farmers believes that there needs to be clear, effective and formalised communication pathways between the APVMA and Agvet chemical stakeholders.

For the purposes of this submission, approval means registration of a chemical product or approval of a constituent; and Agvet product means a chemical product, or a constituent.

General Comments

Consultation Process

Firstly NSW Farmers seeks to make comments regarding the process of consultation undertaken for the Bill. Whilst the proposals leading up to the development of the Bill has engaged industry stakeholders since early 2011, such as the Initial Bill in late 2011/early 2012, the period upon which the Bill has been placed upon exhibition has been prohibitively short. The extent of the re-drafting undertaken since the Initial Bill; and the period of time lapsed since the consultation on the Initial Bill closed and the Bill was released for consultation, are factors which reinforce this view.

This has been compounded by the lack of guidance material provided by DAFF with the Bill. In particular the failure to produce an explanatory memorandum, as done for the Initial Bill, has reduced the capacity of industry participants to cover the impact of the re-drafting that has occurred in the period since consultation on the Initial Bill was closed.

Benefit Cost Analysis

In NSW Farmers' submission in response to the Initial Bill, a concern was outlined at the failure to undertake a detailed benefit cost analysis of the reforms. This position was driven by an underlying concern that the trade exposed nature of Australia's agricultural industry; this failure meant an inability to consider whether the trade competitiveness of Australia's farmers was decreased as a result of the reforms.

CropLife Australia has recently released a report, commissioned from Deloitte Access Economics, outlining that the impact of the direct costs of the implementation of the Government's reform agenda, which are \$8 million; result in a negative impact of \$21 million dollars upon the Gross Domestic Product of Australia. However, even this figure excludes opportunity costs resulting from lost productivity due to registrants delaying the introduction of new Agvet chemicals into Australia; and is only based on the costs of funding the implementation of the transition to the reforms. Costs of administering the core reforms of Bill are greater again.

As such, whilst the Australian Government's Best Practice Regulation Handbook outlines that a formal benefit cost analysis is not required for all regulatory proposals; NSW Farmers would argue the possible impacts of the reforms contained within the Bill justify the development of a full quantitative analysis.

Recommendation:

NSW Farmers recommends that prior to further consideration of the reform proposals within the Bill, that a formal quantified benefit cost analysis should be undertaken and provided to industry for consideration.

Schedule 1 – Approval Processes

Statutory Objectives and Guidance on Implementation

General

Part 1, Division 1 of the Agvet Code, headed ‘Object, definitions etc’ may be seen as being established by the Legislature, to provide guidance to decision makers and the judiciary as to the ‘purpose or object underlying’ the code.²

On this basis, NSW Farmers does not oppose the concept of introducing s 1A into the Code; however seeks to make the following comments as to the proposed content.

Triple Bottom Line Outcomes

NSW Farmers is concerned that the net impacts of a regulatory decision by the APVMA in consideration of an approval, are not adequately taken into consideration.

On this basis NSW Farmers recommends that a new sub-section be inserted within s 1A to direct decision makers to the consideration of the net environmental impact of a decision. This should specifically look at the impact of the target pest upon the environment if unmanaged, or where an alternate chemical product is available, the impact of this product on the environment, and impact of failure to approve on the management of resistance to available pesticides and therefore any resultant impact the pest makes on the environment.

Recommendation:

To implement a net benefit approach to the APVMA’s approval process, NSW Farmers recommends the addition of a sub-section with the objective of the sample sub-section reproduced below:

Recognises that the regulation of chemical products and their constituent products should take into account the net impact of any regulatory decision upon the environment, taking into account the impact of the target pest if left unmanaged, or where alternate products are available, the impact of their use on the environment, and the value of maintaining resistance management strategies to managed long term pest control.

NSW Farmers has suggested appropriate amendments to the Safety Criteria elsewhere in the submission.

² Acts Interpretation Act 1901 (Cth), s 15AA.

“Unmanageable Risk” (Section 1A (e))

NSW Farmers believes that the policy intent of managing the risks of using active constituents and chemical products to human health and the environment, with the addition of net impact proposed above, is adequately articulated within 1A (b)-(d).

However, the utilisation of the term ‘unmanageable risk’, which is not defined within the Code, poses concern to NSW Farmers. This is on the basis that as part of the underlying purpose of the Code, that ‘products that pose *unmanageable* risks’ [emphasis added] are not appropriate, a decision maker is required to, as far as the language of the specific provision within the Code enables, to select an interpretation which implements this purpose.³

As a result, it is possible that this guidance will leave the interpretation of the Code open to subjective decision making, reducing clarity and consistency of decision of regulatory approvals made under the Code.

Recommendation:

NSW Farmers recommends the omission of 1A (e) from the Bill.

Safety, Trade, Efficacy, Labelling Criteria (Item 32)

NSW Farmers supports the streamlining of the Code’s drafting through the provisions proposed in item 32, which aggregate the approval criteria for safety, trade impacts, efficacy and labelling.

Safety Criteria – Risk Management

While NSW Farmers acknowledges that the terminology incorporated within s 5A for the safety criteria replicates the present Act’s approval criteria, it considers that the amendments provide the opportunity to re-express the safety criteria based on risk management principles. On this basis, NSW Farmers recommends the amendment of s 5A (1) (a), replacing references to ‘hazard’ with ‘risks’.

Recommendation:

NSW Farmers recommends the amendment of s 5A (1) (a) by omitting references to ‘hazard’ and replacing it with ‘risks’.

Safety Criteria - Net Environmental Impact

As outlined above, NSW Farmers believes that the APVMA’s approval regime would be more effective, as well as perceived to be more effective, if it took into account the net impacts upon the environment of any approval. Such a process would determine any impact that the target pest species may have upon the environment, or alternatively the impact of available alternatives upon the environment, as well as the cost to the

³ Catriona Cook et al, *Laying Down the Law* (7th Ed) [8.9] – [8.13].

environment of failing to manage resistance of pests to products. These impacts would then offset any negative impact which is attributed against the application for approval/registration being considered.

Recommendation:

NSW Farmers recommends the amendment of the Safety Criteria to implement a net benefit approach in the decision making process, by the addition of a paragraph to s. 5A (3) (a):

(xx) the net impact of the product and its residues in relation to relevant organisms and ecosystems. Including any impact of the target pest if unmanaged, or alternative control measures upon the environment; and the need to maintain resistance management strategies.

Risk Based Framework (Item 33)

Guidelines

In its submission to the Initial Bill, NSW Farmers reinforced its support for a regulatory approvals system which is based on the assessment of risk using sound, evidence-based science that is transparent and consistent. At that stage, NSW Farmers recorded its disapproval at the proposal to implement risk management approval processes by removing mandatory trade and efficacy considerations for an approval. In the alternative, the submission pointed to the Regulation Impact Statement (RIS) prepared for the Better Regulation reform, which outlined that statutory provisions were required to enable a risk framework to be the basis of the APVMA's decision making.

On this basis, NSW Farmers supports the introduction s 6A, which allows the APVMA to establish guidelines, which it must then have regard for when considering an approval. However, NSW Farmers is concerned that the Bill does not make it mandatory for the APVMA to establish guidelines, nor does it specify how the APVMA must consult with impacted industry in the establishment of, and maintenance of the guidelines.

While NSW Farmers acknowledges the APVMA's demonstrated commitment to seeking feedback on its draft risk compendium, which is to form the first of these guidelines; there is no statutory compulsion for this to be the status quo for future guidelines or revisions.

Recommendation:

NSW Farmers recommends that proposed section 6A be amended so that:

- The APVMA's discretion to develop guidelines is removed, and replaced by a statutory mandate to do so; and
- Standard terms of consultation in the development and revision of the guidelines are required. This should include a minimum 90 day public exhibition period of any new guideline or amendment.

Streamlined Approval Process

In its submission to the Initial Bill, NSW Farmers reinforced its support for reforms which create a more efficient and timely registration system, avoiding unnecessary delays for industry on the basis of the benefit that accrues to farmers through reduced cost and facilitating new and innovative chemistry. On this basis, NSW Farmers supported the use of electronic communications to facilitate faster, more efficient approvals processes.

The submission however opposed proposals which increased the rigidity of approvals processes. This was on the basis that any increase in costs resulting from the APVMA mandatorily refusing an application, may impact negatively in on making new and innovative chemistry available to industry.

Use of Electronic Communications (Item 143)

NSW Farmers retains its support for the use of electronic communications as a means to improving the efficiency of the APVMA approval processes.

Registration and Approvals and Variations (Items 34 – 37; 40)

NSW Farmers recognises that in response to industry concerns on the requirements of the APVMA to refuse an application in certain circumstances, a modicum of flexibility has been introduced to the revised Bill by the operation of proposed s 11 (4). This enables the application to be amended by the APVMA after it passes preliminary assessment.⁴

In its invitation to comment, DAFF has characterised the flexibility within s 11 (4) as providing the capacity to the 'APVMA to address issues with applications after preliminary assessment where it would be more efficient to correct a deficiency rather than refuse the application'. However, it remains mandatory for the APVMA to refuse an application that it deems to not have met the application requirements.⁵ It is only after this approval that the APVMA is able to assist in rectifying other defects that may arise in the application.

⁴ Agricultural and Veterinary Chemical Legislation Amendments Bill 2012 (Cth) Schedule 1, Item 34, s 11. See Schedule 1, Item 40, s 28 for variation of particulars and conditions.

⁵ Agricultural and Veterinary Chemical Legislation Amendments Bill 2012 (Cth) Schedule 1, Item 34, s 11.

Minor Use Permits (Items 100 - 106)

Through s 110A, the revised Bill introduces greater flexibility to the process of approving a permit. This has been done through giving the discretion to the APVMA to identify defects in an application for a permit, and providing a one month period for these defects to be rectified. For permits, the mandatory refusal of the application is limited at preliminary assessment to circumstances in which the defects where the 'APVMA is not satisfied that defects in the application can reasonably be rectified'.

NSW Farmers is pleased that an effort has been made to accommodate its concerns with regard to the impact that the mandatory refusal provisions would have on industries reliant upon minor use permits to access chemical products. However, on the basis that the criteria for mandatory refusal were introduced to improve efficiencies in the application process, NSW Farmers believes that the provisions should be amended to reflect this objective. Further, on the basis of seeking efficiency, NSW Farmers does not believe that there should be a distinction between the thresholds for approvals for products, constituents and minor use permits.

Recommendation:

NSW Farmers recommends amending the threshold for mandatory refusal, described within proposed s 110A (4) (a) to:

The APVMA determines it would not be more efficient to rectify the defects as described in sub-section (3).

This provision should then be utilised across the preliminary assessment process for minor use permits, registration, approvals and variation of relevant particulars and conditions.

Limitations on Information

NSW Farmers is concerned that the Bill, through the establishment of the application criteria, and provisions restricting the APVMA's capacity to take into account other information. As such the limitations may preclude the APVMA meeting its charter of a being a 'structured and scientific, evidenced based' independent evaluator of chemicals when making regulatory decisions.

Further, there may be circumstances in where information that the APVMA has not requested may be critical to its consideration on an approval, and it would be more efficient to take into account the information as part of an existing application, rather than reject it and require the applicant to make a new application.

On this basis, NSW Farmers considers that provisions to enable greater cooperation between the APVMA and applicants to enable the APVMA to consider this information where it would be a more efficient course of action.

Recommendation:

NSW Farmers recommends that a provision is made in either s 159 or s 160A (4) to require the APVMA to consider whether it would be more efficient to receive and consider new information, as opposed to rejecting an application.

Varying particulars and conditions – (Item 40)

NSW Farmers endorses the provisions within s 27, which would enable a person, such as an industry group, to apply for the variation of a registration of an Agvet product, and the approval for the products label, as a means to providing a mainstream pathway to provide ‘minor use industries’ with access to registered Agvet product.

NSW Farmers’ agrees with the comment made by DAFF that this will also ‘assist in the operation of any future minor use initiative’.⁶

Chemical Reconsideration (Item 41- 45)

NSW Farmers has supported the process of chemical review, as being the appropriate means of prioritising resources to ensure that available chemical products are safe; and is supportive of reforms which improve the chemical review program to ensure timely completion of reviews.

Engagement of impacted industry (Item 45)

It is the view of NSW Farmers that the chemical review program would benefit from better engagement with sectors of industry which may be impacted by the outcome of review. This engagement is likely to lead to greater understanding and acceptance of the review process and therefore of outcomes of individual chemical reviews.

To achieve this outcome, NSW Farmers recommends amendment to the discretionary power of the APVMA proposed within s 32 (3) – (4) to ‘inform’ and consult with persons it considers appropriate.⁷ In particular, NSW Farmers recommends that this be amended to require the APVMA to establish an industry reference panel, which is made up of the impacted industry members of Plant Health Australia and Animal Health Australia, upon a proposal to reconsider a constituent or product.⁸

⁶ Department of Agriculture, Fisheries and Forestry ‘Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012: REVISED EXPOSURE DRAFT, September 2012’, 7.

⁷ Agricultural and Veterinary Chemical Legislation Amendments Bill 2012 (Cth) Schedule 1, Item 45, s 32 (30 – (4).

⁸ For Plant Health Australia Industry Members see <http://www.planthealthaustralia.com.au/index.cfm?objectid=0AC61648-A6F0-143E-03122DFA1127D039>; for Animal Health Australia Industry Members see <http://www.animalhealthaustralia.com.au/about-us/members/>.

Recommendation:

NSW Farmers recommends that when the APVMA proposes to reconsider an approval or registration, that is required to constitute an industry reference panel, with representation from industry members of Plant Health Australia and Animal Health Australia representing industries that may be impacted by the reconsideration.

Targeted Chemical Reconsideration (Item 45)

NSW Farmers supports the proposal within s 32 (5) to enable the APVMA to limit the proposal to reconsider a registration or approval to target specified matters. In the determination of what matters should be subject to reconsideration, NSW Farmers recommends the engagement of the proposed industry panel in the process.

Holders of Permits (Item 109 – 110)

NSW Farmers holds concerns over the disqualifying provisions associated with the issuing of permits under the proposed s 112 and 112A, on the basis that the breadth of these proposed provisions may have unintended consequences for organisations holding permits on behalf of industry.

Convictions

Of particular concern is:

- The unqualified provisions in relation to a conviction of ‘an offence against an Agvet law’,⁹ or ‘relating to chemical products’;¹⁰ and
- The disqualification of an organisation if a person ‘who makes, or participates in making decisions that affect the whole, or a substantial part, of the proposed permit holder’s affairs’.¹¹

The result of these provisions combined would be to disqualify an industry body, if a farmer member, sitting on the board of that body, had been convicted even of a minor offence under the control of use legislation in the relevant jurisdiction.

Suspension or cancellation of permit

Likewise, the disqualifying provision of having a ‘permit issued under an Agvet law suspended or cancelled’,¹² without further qualification is likely to have unintended

⁹ Agricultural and Veterinary Chemical Legislation Amendments Bill 2012 (Cth) Schedule 1, Item 109, s 112 (3A) (b) (iv); Item 110, s 112A (3) (b) (iv).

¹⁰ Agricultural and Veterinary Chemical Legislation Amendments Bill 2012 (Cth) Schedule 1, Item 109, s 112 (3A) (b) (v); Item 110, s 112A (3) (b) (v).

¹¹ Agricultural and Veterinary Chemical Legislation Amendments Bill 2012 (Cth) Schedule 1, Item 109, s 112 (3A) (b) (ii); Item 110, 112A (3) (b) (ii).

¹² Agricultural and Veterinary Chemical Legislation Amendments Bill 2012 (Cth) Schedule 1, Item 109, s 112 (3A) (b) (x); Item 110, 112A (3) (b) (x).

consequences. This is on the basis that the Code, in its current operation, and as proposed to be amended, contains a number of conditions for which suspension or cancellation of a permit must be undertaken by the APVMA. This includes reasons which do not contain fault elements on the behalf of the permit holder; such as for the reason that the product of constituent is no longer considered to meet requirements of the safety criteria.¹³

NSW Farmers believes that the provisions of conviction for an offence against Agvet law or relating to chemical products and for the suspension or cancellation of a permit should not be retained. If they are retained, NSW Farmers believe that they must not remain as mandatory reasons for refusing the application. Rather, the APVMA should be provided with discretion to consider the nature of any conviction, or suspension or cancellation prior to refusing an application on the grounds of the character of the permit holder.

Recommendation:

NSW Farmers recommends that the provisions disqualifying an organisation from being able to hold a minor use permit on the basis of:

- an offence committed by a person, who makes decisions on behalf, or participates in the decision making process of the organisation, under Agvet law, or another offence relating to chemicals; and
- the suspension or cancellation of a minor use permit.

are removed. If these disqualifying provisions are not removed, they should no longer constitute mandatory reasons for refusing an application, and the APVMA should be provided with the discretion to consider the nature of the conviction, or suspension, or cancellation prior to refusing an application on the grounds of the character of the applicant.

Use of International Data and Regulatory Decisions (Item 156 – 166)

NSW Farmers' response to the Initial Bill was supportive of the use of overseas information regarding the registration and approval of products and constituents to provide efficiencies to the APVMA's operations. However this support was tempered by the need to ensure that the differences in the Australian environment and farming production systems are adequately ground truthed prior to any overseas evidence being relied upon.

To ensure that this is done to a level of scrutiny that provides confidence within impacted industries, NSW Farmers recommends that the APVMA be required to consult with a reference panel consisting of the industry members of Plant Health Australia and Animal Health Australia representing industries that may be impacted by the use of international evidence.

¹³ *Agricultural and Veterinary Chemicals Code* ss 118 (1); 119 (1).

Further to the initial caution on the need for international evidence to be ground truthed, NSW Farmers is not supportive of the use of international regulatory decisions, *ipso facto*, in domestic regulatory decision making. Rather, NSW Farmers believes an evidenced based regulatory framework implemented by the APVMA should independently examine data, to the extent it is relevant to the domestic environment and proposed use, in the undertaking of an consideration of the requisite approval criterion.

Recommendation:

NSW Farmers supports the use of evidence generated in foreign jurisdictions on the basis that it has been ground truthed using an industry reference panel.

NSW Farmers does not support the use of foreign regulatory decisions in any consideration by the APVMA.

Schedule 2 – Re-Registration Framework

General Comments

In response to the Initial Bill, NSW Farmers outlined that they were opposed to the continuance framework proposed. The major reasons for this position were the direct cost of such a scheme, as well as the indirect cost of regulatory burden. This includes the risk that safe and effective chemicals may be deemed by registrants as not being economic to re-register, leading to a net loss of chemical product, directly impacting on farm productivity.

In consideration of the evidence regarding these two aspects, at that time, NSW Farmers noted:

NSW Farmers is concerned that in the RIS' consideration of the new continuance scheme failed to outline a benefit cost approach against the existing chemical review scheme, with its only comparison instead directed to European and American models. As such there is no ability to conclude whether the proposed system will benefit registrants, end users of agvet products, or the general public, when compared with the status quo.

This concern has been heightened by the findings of Deloitte Access Economics report commissioned by CropLife Australia, given the APVMA's own estimation that the re-registration process would cost levy payers \$2 million dollars annually, in addition to the commercial costs associated with holders developing the necessary information for re-registration.

On this basis, NSW Farmers repeats the recommendations that it made prior to considering specific elements of schedule 2:

- that the Government should not proceed with the proposed continuation [re-registration] of approvals and registration scheme implemented by Schedule 2 of the Bill.
- that Government funds public good arising from the operation of the proposed continuance [re-registration] scheme.
- that transitional measures be implemented under the Bill to ensure no loss of Agvet products to the agriculture industry during the continuance [re-registration] scheme's implementation.

NSW Farmers seeks to re-emphasise its support for the Chemical Review program as the most appropriate risk based mechanism to prioritise the assessment of existing Agvet product to ensuring the safety, efficacy and impact upon trade of Agvet products. As a result of the implementation of this policy, more of the APVMA's resources will need to be moved into the process of conducting re-registration, at the cost of registrants, and ultimately farmers and the general public.

Recommendation:

NSW Farmers opposes the introduction of the proposed re-registration scheme without full industry consultation on a benefit cost analysis.

NSW Farmers supports the continued use of the Chemical Review program as the most appropriate way to undertake a risk based process to ensure the safety, efficacy and confidence of trade when using Agvet products.

Re-approval or Re-registration

Period of Registration/Approval

Establishment of period of registration/approval (Schedule 1 Item 39 and 45)

Sections 19, 20 and 34B of the Bill outline that the registration of an Agvet product, must be set by the APVMA for a period between 7 and 15 years. Presently draft regulations are open for consultation which, when finalised, will provide guidance to the APVMA on how to exercise this discretion. In considering these draft regulations, it is apparent that the recommendations are a departure from the risk management approach which is the foundation of Australia's agricultural chemical regulation framework.

Recommendation:

NSW Farmers recommends that any regulation providing guidance to the APVMA on the establishment of a period of registration, must be based on risk management principles, and not hazard based.

Variation of the duration of registration/approval (Item 5)

For the reasons outlined above, NSW Farmers rejects the use of decisions of foreign regulators *per se*, in the registration framework for Agvet products and constituents. With particular regard to the proposal to vary the length of the approval, based on a negative regulatory decision of two prescribed countries, NSW Farmers considers this to be a poor evidence base upon which to prioritise the resources of the APVMA. Even with the thresholds established within s 47A (b), a consideration of the range of methodologies through which foreign regulatory decisions are made in the prescribed countries, reveals the use of foreign regulatory decisions as being populist over risk based.

If the current proposals for variation of the period of registration/approvals are to be included within the Bill, it should be limited to foreign regulatory decisions taken within the period of registration. This is on the basis that any international decisions prior to the re-registration will have been considered.

Recommendation:

NSW Farmers does not support the use of foreign regulatory decisions as a sound basis for varying the registration of an Agvet product, and recommends that s 47A be omitted from the Bill

However, if s 47A is not omitted it should be amended to clarify that the seven year period recommences whenever the Agvet product is re-registered.

Test for re-registration

Proposed s 29F requires that the APVMA must re-approve/re-register a constituent or product, 'unless it *appears* to the APVMA that there are *reasonable grounds* to believe that the constituent does not meet the safety criteria' [emphasis added]. NSW Farmers considers that the qualifying threshold of 'appears' leads to ambiguity surrounding the task undertaken by the decision maker.

Recommendation:

NSW Farmers recommends omitting the term 'appears' from s 29F so that the proposed test for re-registration/re-approval reads as marked up below:

... unless ~~it appears to the APVMA that~~ there are reasonable grounds to believe... [the constituent/product] does not meet the safety criteria.

Reconsideration upon failure to re-register/re-approve

If the re-registration/re-approval scheme is to be implemented, NSW Farmers agree that placing the product/constituent into the chemical review program as being an appropriate outcome upon failure to achieve re-registration/re-approval, as proposed under s 29H.

Schedule 3 – Enforcement

NSW Farmers seeks to reaffirm the position it made on the initial draft Bill that an increased focus on compliance mainly provides a public good, as opposed to one that may be captured by market participants. On this basis, NSW Farmers believes that these functions are most appropriately funded from consolidated revenue.

Schedule 4 – Data Protection

NSW Farmers seeks to affirm the position it made on the initial draft Bill that the measures contained within the Bill appropriately finds the balance between return upon investment to primary registrant companies, and the benefit that accrues to end users as a result of competition.