Submission to the Rural and Regional Affairs and Transport Legislation Committee Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014

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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.

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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 a submission to the Senate's Rural and Regional Affairs and Transport Legislation Committee's inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (the Bill) on behalf of its membership.

NSW Farmers, endorses the Federal Government's policy for agricultural and veterinary (together 'agvet') chemicals. This policy appropriately focuses on maintaining a risk management approach to regulation, informed by the best available science, with the twin objectives of maintaining safe and effective use of agvet chemicals, while providing agricultural and horticultural producers with productivity enhancing technologies. Key to the Government's commitments to achieving these objectives is the proposed repeal of the uncommenced re-approval and re-registration, removing red tape from registration processes that reduce access to safe and effective chemicals, and facilitating access to minor use chemical applications.

On this basis NSW Farmers supports the passing of the Bill without amendment.

Agricultural and Veterinary Chemicals Policy

NSW Farmers has been an active participant in the development of agvet chemical policy at a state and federal level over many years. The conclusion drawn by Deloitte Access Economics that up to 68% of the value of Australia's horticultural, grains and fodder crop production is achieved as a direct result of crop protection products supports this level of engagement.[1]

It is the view of NSW Farmers that good policy is needed in order for Australia to maintain the levels of high productivity that crop protection products offer to Australian agriculture and the economy more broadly. This is mainly because 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.[2]

As such, any costs and impediments associated with the Australian regulatory framework for access to agvet chemicals may result in delays or the withholding of product from the Australian market due to the lack of commercial incentive. These delays, particularly in fostering replacement tools where access to existing products are withdrawn for either commercial or regulatory reasons, result in reduced productivity and profitability of Australia's farmers and the communities that they contribute to.

[1] Deloitte Access Economics (2013) 'Economic activity attributable to crop protection products' (commissioned paper CropLife Australia) 3.
[2] Deloitte Access Economics (2012) 'Review of APVMA Cost Recovery Discussion Paper', 13.

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NSW Farmers has determined industry policy with regard to the need of end users in the agvet 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;
- 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; and
- has clear, effective and formalised communication pathways between the APVMA and peak representatives of end user industries.

1. Schedule 1 - Removal of re-registration and re-approval

During consultation that led to the development of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* NSW Farmers indicated concern over the proposed introduction of a mandatory re-registration and re-approval scheme (re-registration scheme). These concerns were focused on the intent of the re-registration scheme to move away from a regulatory scheme based on risk management principles and the cost implications that the scheme would have on farmers.

With particular regard to the latter of these concerns, NSW Farmers notes that if implemented the scheme would cost end users of agvet chemicals close to an additional $2 million per annum in the APVMA's administrative costs which would be recouped in levies. Costs would also be borne by farmers with the direct costs of compliance with the scheme incurred by registrants being passed on to farmers. In addition to these direct costs, NSW Farmers is particularly concerned at the likely opportunity costs that would have been borne by farmers in reduced productivity caused by removal of safe and effective chemicals, and slower introduction of new chemicals due to a higher R&D spend on maintaining registration in Australia.

1.1 Chemical Review Program

NSW Farmers continues to support the chemical review program as being the appropriate policy instrument to ensure that chemicals are safe and effective. This is because it enables the APVMA to prioritise its resources to the chemicals posing the highest risk to human and environmental safety. The chemical review program does this by the APVMA constantly reviewing science based literature and international regulatory decisions and any reporting of adverse experiences with chemicals and residues.

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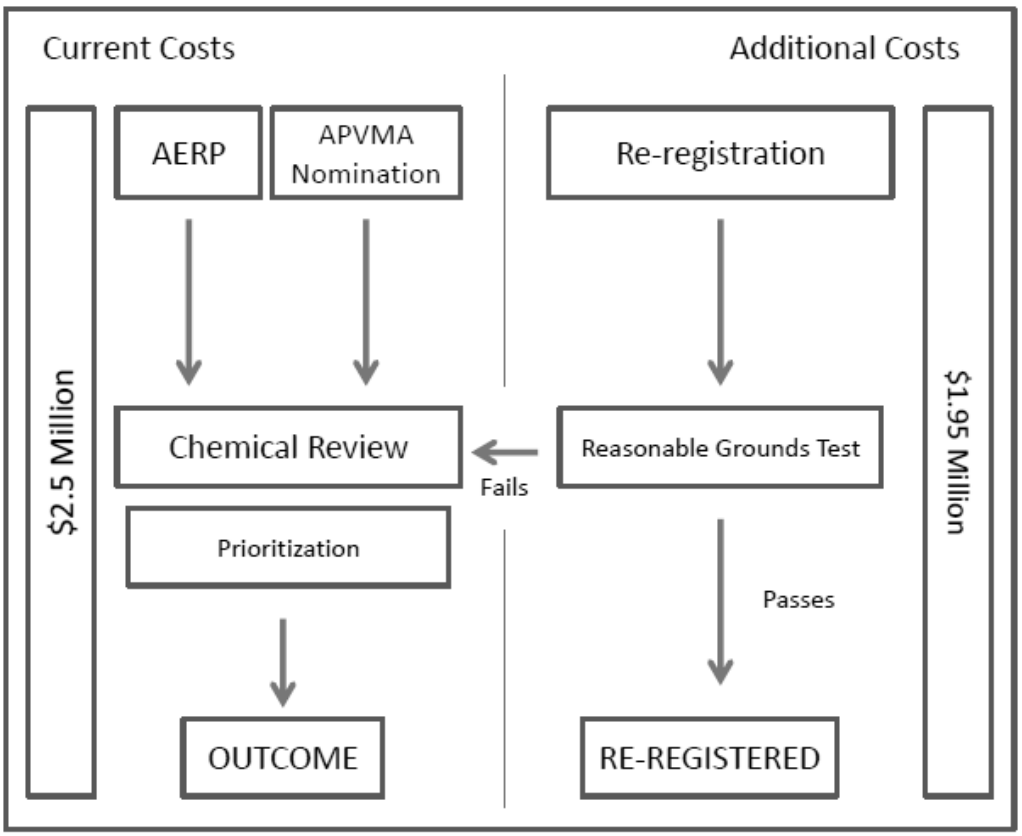
In support of this position, NSW Farmers has undertaken an analysis of chemical review against that of the re-registration/re-approval scheme which is scheduled to commence on 1 July 2014. This analysis shows that the main operation of the proposed scheme would be to duplicate those processes that are undertaken as part of the ongoing nomination process that the APVMA undertakes as part of the actions it routinely undertakes in the nomination of chemicals for the review program.

As Figure 1 demonstrates, the APVMA already utilises systemic and evidence based processes to determine, on a risk basis, whether a chemical should be scheduled for Chemical Review through the adverse experiences reporting programme (AERP) and the broader administration of the nomination of chemicals for the chemical review program. The duplication of regulation and the prima facie additional costs of the uncommenced re-registration and re-approval scheme can be seen by displaying them alongside the current systems used by the APVMA to ensure that registered products remain safe and effective when used in accordance with approved labels. Further details on these processes are provided below.

Figure 1 Chemical Review vs Re-registration scheme[3]



1.1.1 Adverse Experience Report Program

The AERP operates through the reporting of adverse experiences by a member of the general public, from control of use regulator in a state or territory, or by a product

[3] Figures taken from the *Cost Recovery Discussion Paper 2011* and the *Cost Recovery Impact Statement 2012 of the APVMA.*

registrant in accordance with the duty to report to the APVMA any adverse experiences that they become aware of adverse experience associated with a chemical they are the registrant for.[4] Reports are assessed by APVMA to determine whether the adverse experience is related to the use of or exposure to the product or not. The APVMA may rely on advice from other Australian government agencies and published material available from similar reports in addition to relevant internationally published scientific literature.

The adverse experience reports are streamlined based on the degree of risk to human health, the environment and concerns of product efficacy. They are ranked from high to low categories accordingly. Collated information, including information searches, are presented to the *AERP Ag Advisory Committee* which consists of a panel of experts who determine whether there was an association between the adverse experience and the product of active constituent.

All high priority reports involving human health are assessed independently by the Department of Health and Aging and the APVMA considers the proposal in determining corrective action where necessary. The AERP process may only make recommendations on corrective actions. Enforceable corrective actions are not possible unless a formal review has been conducted. If doubts regarding the safety of the product to human health, the environment or the efficacy of the product are present the product or active constituent will be subject to a formal chemical review where enforceable corrective actions may been made.[5]

1.1.2 Nomination for Chemical Review

Presently the APVMA can accept external nominations for review, or self refer a nomination for review as a result of its ongoing intelligence into experience and literature on chemicals. The APVMA will self nominate a chemical for review on the basis of:

- international regulatory decisions
- international regulatory scientific assessment reports
- adverse experience reports associated with use of product in accordance with directions for use
- residue detections associated with use of product in accordance with directions for use
- compliance intelligence
- high quality peer-reviewed scientific literature
- information submitted to the APVMA in compliance with existing statutory obligations
- information obtained by state and territory agencies in their administration of control-of-use functions.

[4] APVMA 2003, Adverse Experience Reporting Program For Agricultural Chemicals Public Information Package. Accessed at: http://www.apvma.gov.au/use_safely/adverse/docs/information_package_AERP_ag.pdf

[5] Ibid. p. 20

Decisions of overseas regulators are continuously monitored by the APVMA. Decisions from other jurisdictions are not necessary conditions to warrant conducting a chemical review in Australia. Rather the APVMA review these decisions adverting itself to the following considerations:

- differences in the use of the chemical (sales volumes, use patterns, use rates)
- differences in environmental and agronomic factors (rainfall, method of application)
- differences in pests and diseases of importance
- differences in animal husbandry techniques
- differences in the properties of the products supplied in the different countries (formulation)
- differences in risk management/risk mitigation assessment and/or legislative frameworks.

1.1.3 Prioritizing Chemical Reviews

The prioritization of the chemical review is based on advice from internal and external advisory agencies available to the APVMA which include the Office of Chemical Safety, Department of Health and Aging and the Department of Sustainability, Environment, Water, Population and Communities. All chemicals referred to chemical review including those as an outcome of the re-registration/re-approval process utilize the same risk based prioritization system[6]. Review prioritization is based on the following key criteria[7]:

- Human health (toxicology and occupational health and safety)
- Environment
- Residues and trade
- Efficacy
- Target animal and crop safety

1.2 Perverse outcomes of re-registration and re-approval

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 re-registration/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.

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[6] Australian Pesticides and Veterinary Medicines Authority 2012, p.25 Chemical Review Framework. Accessed at: http://www.apvma.gov.au/about/work/better_regulation/docs/chemical_review_framework.pdf

[7] Australian Pesticides and Veterinary Medicines Authority 2012, p.23 Appendix 1 – System to prioritise chemicals nominated for reconsideration. Chemical Review Framework. Accessed at: http://www.apvma.gov.au/about/work/better_regulation/docs/chemical_review_framework.pdf

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Recommendation 1

NSW Farmers recommends the changes proposed to the AgVet Code contained within Schedule 1 that will repeal the uncommenced re-registration and re-approval scheme are passed without amendment.

2 Schedule 1 Less frequent renewal of registration

It is the position of NSW Farmers that the reduction in administrative burden upon registrants participating in the National Registration Scheme is beneficial to agricultural and horticultural end users as it reduces costs passed down into the retail cost of chemical inputs. Further reduced complexity of administration where it does not impinge on safety or efficacy reduces the barriers to investment in Australia as a destination for the commercialisation of agricultural and veterinary chemical technologies.

On this basis NSW Farmers supports the proposed amendments that would enable flexibility in the renewal period of a product's registration.

NSW Farmers believes the development of the options for renewal periods should be undertaken with the peak groups representing the manufacturers of crop protection and animal health products to minimise the benefit this proposal will present to the NRS.

Recommendation 2

NSW Farmers recommends that the provisions within Schedule 1 that will enable less frequent renewal of registration be passed without amendment.

3. Schedule 2 Chemical product quality

NSW Farmers supports the proposed amendments to s 99 of the AgVet Code proposed in the Bill which would provide the APVMA with an appropriate power to seek the provision of an analysis of a chemical product being provided into the market. This power will enable the APVMA to ensure that product being supplied into the market place continues to meet the composition and safety standards that the APVMA considered at registration.

In supporting this amendment, NSW Farmers notes that reasonable restraints will be retained upon the APVMA's power, in that it must hold a reasonable suspicion prior to exercising the power.

However NSW Farmers urges caution with regard to mandating specific reporting of compliance activities, without a broader consideration to what are the measures that best demonstrate regulatory efficacy. For example, in the field of occupational health and safety, NSW Farmers is of the belief that some stakeholders have placed an over reliance on prosecution activity as a measure of regulatory efficacy, rather than the measures that display a depth of compliance across duty holders.[8]

[8] See National Farmers Federation, Submission No 172 to *the National Review into Model OHS Laws*, 11 July 2008, 8-9; available online at <https://submissions.deewr.gov.au/sites/submissions/ohsreview/pages/ohsreviewsubmissions_151_200>.

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NSW Farmers believes that a broader dialogue with industry is required to determine the appropriate metrics that should be reported to demonstrate and benchmark the regulatory efficacy of the National Registration Scheme.

Recommendation 3

NSW Farmers recommends that the proposed amendments to s 99 of the AgVet Code proposed within the Bill are passed without amendment.

4. Schedule 2 - Simpler variations to approvals and registrations

NSW Farmers supports the proposal to streamlining regulatory approvals for applications seeking simple variations to registrations and approvals through the amendments proposed to Division 2A of Part 2 of the AgVet Code. This proposal will enable the APVMA to streamline approvals for types of variations that have been prescribed either by regulation or by a legislative instrument gazetted by the APVMA based on the fact that the type of variation will not result in the product or constituent no longer meeting the safety and efficacy criteria and other legislative requirements of the AgVet Code. NSW Farmers believes that the proposal will enable the APVMA to focus its activities on higher risk applications improving the efficiency of the National Registration Scheme.

In respect of the types of variations that should be included within the variations prescribed, NSW Farmers recommends that these should be determined in conjunction with the peak representatives of the crop protection and animal health product registrants.

Recommendation 4

NSW Farmers recommends that the proposed amendments to Division 2A of Part 2 of the AgVet Code contained within the Bill are passed without amendment.

5. Schedule 2 – amendments to the Food Standards Australia and New Zealand Act 1991

NSW Farmers supports the amendments proposed to the *Food Standards Australia and New Zealand Act 1991* (Cth). The impact of lags between the establishment of a new APVMA MRL and the Food Standards Code was documented by the Productivity Commission's report into the Plastics and Chemical Industries. In particular, these lags may lead to a position in which farmers are able to apply a particular chemical, yet not able to sell the produce due to breaches of the Food Standards Code.[9]

Conversely, without the changes Australian farmers may also be disadvantaged where there is a lag in amending the Food Standards Code when the agvet MRL is amended due to health concerns restricting the use of chemicals. This situation would allow the continued importation of food which is in breach of the safety standards that are applied to domestic production.

[9] Productivity Commission, *Plastics and Chemicals Regulation* (Research Report, July 2008) 133.

Recommendation 5

NSW Farmers recommends that the proposed amendments to the *Food Standards Australia and New Zealand Act 1991* (Cth) contained within the Bill are passed without amendment.