Better Regulation of Agricultural and Veterinary Chemicals

Submission in Response to the Draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011

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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.

Executive Summary

- That the proposed amendments are not supported by a proper benefit cost analysis, which seeks to analyse the impacts upon end users of agvet products.
- That these reforms should instead be incorporated within the processes seeking to harmonise assessment, registration and control of use of agvet products across State and Federal Regimes.
- That NSW Farmers doubts that the proposed legislative amendments are necessary to implement a risk framework, given that the effect of the amendments is to provide the APVMA with discretion on only two of the criterion considered in approvals and registrations.
- That trade considerations and chemical efficacy must remain mandatory considerations for the granting of an approval to an active constituent, or registration to a chemical product.
- That the Government should not pursue a continuance of registration and approval scheme, which would provide an expiry on all approvals and registrations and require the registrant to make an application for continuation of registration.
- If the Government does continue to pursue the continuance framework, then the "no reasonable doubt" test, which requires the APVMA to continue registration in the absence of a reasonable doubt, is the appropriate test.
- That the streamlined application process, which rejects incomplete applications and removes the ability of the APVMA to consider new information from the registrant during the application process, may affect industry bodies and new entrants to the market who are looking to provide product into small markets. This is due to the fact that the provisions apply to minor use permits, as well as full registration and approvals. As such the flexibility within the current approval process should be maintained. At a minimum it should be maintained for minor use permits.
- The proposal to use of overseas data to improve the efficiency of chemical assessments and registrations is welcomed, however further liaison with industry is required to ensure that the use of this data will adequately account for Australian environments and production systems.
- That the new enforcement regime will act as a disincentive for industry bodies to foster access to agvet product by applying penalties to holders of minor permits.
- That the proposed data protection continues to maintain a balance to incentivise the commercialisation of innovations in chemistry, as well as enable appropriate competition through the availability of generic agvet products.
- If the mechanisms contained within the Bill are carried into law, an early independent review of their operation is required.

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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 comment to the Department of Agriculture, Fisheries and Forestry on the Draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 (the Bill). We have also previously provided comment on 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, 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.

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; and
- minimises the cost of regulation and compliance that may be passed onto agvet chemical users.

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

General Comments

Benefit Cost Analysis

Australia is a relatively small market in the global supply of agricultural chemicals and veterinary medicines (agvet products). As such, it is important that any regulatory framework for the approval and registration of agvet products is constructed to ensure minimal administrative impediments to maintaining the availability of existing chemistry and to introduce new and innovative products. Failure to do so leaves the farming families and businesses behind Australia's $49 billion dollar agricultural industry at a disadvantage in comparison to those primary producers in competitor nations.

Therefore, NSW Farmers believes that in considering the impact of the proposed reforms, that there has been a failure to properly identify the costs and benefits accruing to private industry and to the broader public under both the status quo and full reform scenarios.

National Harmonisation

At the consultation briefings provided by the Department of Agriculture, Fisheries and Forestry (DAFF) it was made clear to those in attendance that the reforms contained within the Bill were being pursued by the Government on the basis that it possesses the constitutional competence to do so. This is despite the fact that significant government and industry resources are currently employed in seeking harmonisation of the assessment, registration and control of use of agricultural and veterinary chemicals across the Federal and State regimes. NSW Farmers believes that a more orderly transition to such harmonisation would have been to incorporate discussions surrounding the reforms within the Bill into the broader reform agenda.

Schedule 1 – Decision making using a risk based framework

Does the Proposed Reform Further Support the Risk Based Framework

As noted in NSW Farmers' response to the 2010 Paper, we support a system in which risk is assessed using sound, evidence-based science and that is transparent and consistent. As such we support the intention by the APVMA to 'develop, publish and apply and overarching risk framework for agvet chemicals'.[1]

In its assessment of the proposed reform, the Regulation Impact Statement (RIS) considers the effect of such an overarching framework, noting involvement not only from the APVMA, but also from the Office of Chemical Safety, Environment and Heritage, and the Department of Sustainability, Environment, Water, Populations and Community.[2] In seeking to achieve the benefits outlined by the RIS, the Explanatory Guide outlines that 'legislation is required to ensure the risk framework is taken into account when the APVMA makes decisions'.[3]

However upon analysis, it appears that the amendments contained within Schedule 1 does not make any explicit provisions to this effect. Rather, the substantive effect of Schedule 1, made in the proposed changes to s 14 and repeated elsewhere, enables the APVMA to utilise discretion in undertaking assessment of trade impact and efficacy of the active/product, whereas previously these were mandatory. If the changes outlined within the Bill are indeed necessary to implement decision making using a risk based framework, NSW Farmers considers that this logically would have extended to all of the conditions established within the current approval process.[4]

Instead the Bill focuses on providing discretion to the APVMA only on the industry critical criterion of trade and efficacy. The importance of maintaining these two elements of approval are dealt with below.

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[1] Explanatory Guide, Draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 (Cth) 10.

[2] Department of Agriculture, Fisheries and Forestry (2011) *Better regulation of agricultural and veterinary chemicals – Regulation Impact Statement*, 15-17.

[3] Ibid.

[4] See the *Agricultural and Veterinary Chemicals Code* s 14 (3) (a) – (h).

Unduly prejudice trade or commerce

Australian agriculture exported over $32 billion dollars of produce in 2010/11,[5] accounting for two thirds of the gross value of farm production.[6] Importantly to NSW Farmers, over $5 billion of Australian agricultural exports originates from NSW.[7]

As outlined within the *Consultation Regulation Impact Statement – A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*, the maintenance of trading relationships and confidence in Australian agricultural produce; and the costs of any such failure to do so, are important elements in the case for the regulation of agricultural and veterinary chemicals.[8] Integral to this role, the registration and approval regime assists in forming an industry wide quality assurance model, which assists the agriculture industry as a whole to meet the market needs of importing countries.

Further, NSW Farmers is concerned that the RIS fails to undertake a benefit cost analysis of the proposal to make the trade assessment discretionary. Noting the high possible cost to industry in loss of export market, NSW Farmers is concerned that the efficiencies envisaged by the removal of the trade requirement are not comparable against this risk.

Recommendation: That trade implications remains a mandatory consideration for the registration of agvet products or approval of active constituents.

Effective when used in accordance with instructions

In considering the criterion that the APVMA use in either granting or refusing an application,[9] NSW Farmers considers the efficacy of an agvet product to be key to the deliberation of adverse effects on humans and the environment from the use of the chemical. This is on the basis that without a guarantee of efficacy, potential under application and other ineffective use of an agvet product may result, or conversely over application.

The consequence of under application or other ineffective use of an agvet product include:

- Increased pest resistance from inadequate application of product, due to reduced kill of target species or organisms. Increased resistance has the consequential outcomes of losses of productivity through losing effective management tools to deal with the target pest. This can lead to related environmental and/or animal and human health concerns. Further, NSW

[5] Australian Bureau of Agriculture and Resource Economics and Science (2011) *Australian Commodity Statistics 2011*, 3.

[6] Ibid, 14.

[7] Department of Primary Industries (2011) *The contribution of primary industries to the NSW economy: key data 2011*, available online http://www.dpi.nsw.gov.au/__data/assets/pdf_file/0007/425437/contribution-of-primary-industries-key-data-2011.pdf

[8] Product Safety and Integrity Committee (2011) *Consultation Regulation Impact Statement – A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*, 6.

[9] *Agricultural and Veterinary Chemicals Code* s 14 (3) (a) – (h).

Farmers supports the concerns raised by the Australian Dairy Industry Council with regard to food safety impacts.

- Resultant behaviour of farmers to the application of agvet products. Through industry confidence in agvet products, and industry led stewardship programs, NSW Farmers believes that there is high compliance with legal frameworks for the use of agricultural chemicals. NSW Farmers fears that if confidence with the use of an agvet product, when used as per label instructions, deteriorates, that a reaction to ineffective chemical use will result in out of label application. This could have resultant environmental and/or human health effects.

The consequence of over application relate mainly to the effect on non-target species, including that of human health and environmental outcomes.

All of the outcomes above lead to a situation in which the availability of chemistry for productive farming becomes compromised.

Further, NSW Farmers is concerned that without mandatory efficacy assessment, market failure will occur with regard to the verification of the attributes of an agvet product. This is characterised by many small users with the inability to verify that a product is the best option available to them within their production system. This may lead to farmers not adopting new and safer agvet products or even more sustainable production systems.

Recommendation – that consideration of product efficacy remains a mandatory consideration for the registration of agvet products or approval of active constituents.

Schedule 2 – Enhancing chemical review arrangements for existing approvals and registrations

NSW Farmers supports a system which ensures that chemical products are safe and the reform aim of improving the current review process to ensure more timely completion of reviews. However we are concerned about the introduction of the "Continuation of approvals and registration" scheme (the continuance scheme) which is introduced in Schedule 2 of the Bill.

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.

Recommendation – that the Government should not proceed with the proposed continuation of approvals and registration scheme implemented by Schedule 2 of the Bill.

Cost of the Continuance of Registration Scheme

NSW Farmers is concerned that the cost of operating the registration continuance scheme will increase the cost of maintaining Australia's system of agvet product approval/registration. This cost will be generated with respect to both low and high risk agvet product due to the requirement for the APVMA to undertake a preliminary assessment of an application for continued registration. Further to this are the costs that are associated with the more intensive submission process contemplated for agvet products which fail to obtain approval under the proposed s 51F of the Code.

Whilst there is no accurate benefit cost assessment which outlines where the proposed benefits of the reform will fall, the RIS outlines that the key benefit are likely to accrue as a public good. As such Government appropriations should be made to fund any public good arising from its operation to reduce the impact of the reform upon agricultural producers.

Recommendation – that Government funds public good arising from the operation of the proposed continuance scheme

Regulatory Burden of Maintaining Registration

In NSW Farmers' response to the 2010 Paper, the capacity of the existing chemical review program was highlighted as being an efficient means of ensuring the ongoing appropriateness of agvet products. In particular, our submission pointed to the ability of the review system to direct resources to the chemicals of highest risk.

Key to the concerns raised at that point in time was that some chemical registrants may consider the cost of data generation and the submission of data to be commercially unviable, particularly when a chemical is generic or close to coming off patent. This may result in registrants not seeking re-registration of their products and disadvantage agvet chemical users if they lose access to effective chemicals which are available to their international competitors. The loss of available chemistry would additionally put more pressure on chemical resistance management programs.

Recommendation – that transitional measures be implemented under the Bill to ensure no loss of agvet products to the agriculture industry during the continuance scheme's implementation.

As stated above NSW Farmers recommends that the proposed continuance framework not be implemented. However if such a scheme is to be implemented, NSW Farmers supports the use of the "no reasonable doubt" test, which requires the APVMA to continue registration in the absence of a reasonable doubt that the agvet product would not continue to meet the key criterion of approval/registration. This is because it continues confidence within the end user industry as to the availability of agvet products, and reduces the cost of implementing the continuance scheme.

Recommendation – that if the continuance scheme is implemented, NSW Farmers supports the use of the "no reasonable doubt" test

NSW Farmers also holds concerns about the ability to access low cost dispute resolution if a person seeks a review of a decision to refuse an application to continue registration. Instead the Bill seeks to clarify that such a decision is only reviewable in the Administrative Appeals Tribunal.

Schedule 3 – Improving quality and efficiency of assessment and registration processes

Electronic Communications

NSW Farmers does not oppose items contained within items [1] to [11] of Schedule 3.

Improvements to processes – "shut the gate" provisions

In response to the 2010 Paper, NSW Farmers supported reforms which create a more efficient and timely registration system, avoiding unnecessary delays for industry on the

basis that they will be of benefit to farmers. In conjunction with this, NSW Farmers noted that the international competitiveness of Australian farmers would be best served by a system that encourages applications for registration of new chemistry.

On this basis, NSW Farmers holds concerns as to the effect of the following proposed requirements:

- that the APVMA must refuse an application that, in the consideration of the APVMA, has not met the application requirements of s 11 (1).
- that the APVMA is restricted to considering information provided to the APVMA within the application, or in respect of any new information sought by the APVMA or required by the Code.

These concerns relate to applications for new and innovative chemistry by registrants, or applications made for minor use permits by industry groups; and the cost associated with having an application refused and then needing to reapply. The latter, in particular, are important for many sectors of the agriculture industry which, due to market failure, have a limited availability of registered product available.

Further, removing the APVMA's ability to be flexible in fostering minor use permits is likely to increase the time it takes for an approval of a permit. NSW Farmers has been informed that presently it takes six months to gain minor use permit approval, and that it is estimated that this time will be lengthened due to the rigidity of the proposed system. This is unacceptable given that minor use permits are normally used due to the absence of registered agvet products as a means to facilitate available product in a timely fashion.

If a disincentive is placed before industry groups to foster access for producers, or conversely the approval process is lengthened, NSW Farmer predicts that producers in smaller industries, most particularly the horticulture and goat industries, will be adversely impacted by the changes.

Recommendation – that the flexibility in the current registration and approval framework be maintained. At a minimum this should be maintained for minor permit approvals.

Improvements to processes – use of overseas data

NSW Farmers supports the proposals which seek to enable more effective use of overseas data, assessments and regulatory decisions by the APVMA, on the basis that it should improve the efficiency of chemical assessments and registrations, providing benefit to Australian agricultural industries. We are pleased that the recommendations made in our response to the 2010 Paper regarding the need to ensure that the differences in the Australian environment and our farming production systems have been incorporated within the Bill. NSW Farmers recommends further liaison with industry to ensure that the application of this provision is implemented to ensure safe guards against denying the Australian agriculture industry of chemicals which are safe and effective to use in Australian conditions.

Recommendation – that further liaison with industry is undertaken to ensure that the application of this provision properly accounts for the Australian environment and production systems.

Schedule 4 – Enforcement

NSW Farmers is concerned about the possible effect on the proposal to introduce s 116A to the Code, which would create an offence for the holder of the permit to contravene a

condition of the permit. As noted above, many industry and grower groups hold permits on behalf of their industry to enable access agvet products, which would be otherwise unavailable due to market failure.

NSW Farmers also specifically supports the argument put forward by the National Farmers Federation that an increased focus on compliance mainly provides a public good, as opposed to one that may be captured by stakeholders. As such these functions are most appropriately publicly funded.

Schedule 5 – Data protection

NSW Farmers supports a balance in the protection of data that has been prepared in support of the registration of agricultural and veterinary chemicals. This balance must recognize the desire of companies to make a return on investment given the high cost of developing, commercializing and registering an agvet product, against the benefit that accrues to end users from the competition created by the availability of generic product.

NSW Farmers believes that the mechanisms contained within the Bill appropriately balance these objectives.

Final Comments

NSW Farmers believes that if the mechanisms contained within the Bill are carried into law an early independent review of their operation is required. Such a review should focus on the effect of the reforms upon end users. Such a review needs to examine:

- whether the reforms have led to the withdrawal, or a reduced incidence of introduction of agvet products into the Australian market place; or conversely whether the reforms have increased the availability of new and innovative agvet product.
- Whether the reforms have resulted in an increase of cost for agvet product paid for by end users.
- The benefits and costs of the reform, which includes opportunity costs resulted from the withdrawal or the reduced incidence of introduction of agvet product.