

**Submission to Department of Agriculture,
Fisheries and Forestry in response to the Better
Regulation of Agricultural and Veterinary
Chemicals Policy Discussion Paper**

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EXECUTIVE SUMMARY

The NSW Farmers' Association supports the key aims of the proposed reforms to:

- *improve the systems that protect human health and the environment;*
- *reduce the regulatory burdens on industry and businesses; and*
- *enhance the Australian Pesticides and Veterinary Medicines Authority's business and operational functions.*

The NSW Farmers' Association makes the following key points:

- *more details are required for the proposed reforms, including how they will be resourced;*
- *reforms should not add unreasonable cost burdens to agricultural and veterinary chemical users but be shared amongst all beneficiaries of the reforms;*
- *the Association supports a transparent and consistent system in which risk is assessed using evidence-based science;*
- *the use of agricultural and veterinary chemicals is an important component of sustainable agriculture and the continued access to them is critical for food and fibre production;*
- *a system which provides greater encouragement of applications for registration of new chemistry would be beneficial to Australian agricultural industries;*
- *improved access to chemicals by small agricultural industries is required and the minor use permit system should be considered as part of the reforms;*
- *efficacy and trade assessment components are valued by industry;*
- *the chemical review process is best managed through a targeted risk-based review program;*
- *in using data generated overseas it is imperative that Australian conditions and farming systems are taken into account; and*
- *agricultural and veterinary chemical users should be considered for the provision of expert advice to the Australian Pesticides and Veterinary Medicines Authority.*

INTRODUCTION

The NSW Farmers' Association (the Association) 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.

The Association welcomes the opportunity to provide comment to the Department of Agriculture, Fisheries and Forestry on the 'Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper' (the Discussion Paper) published in November 2010.

The Association 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 (agvet) chemicals. However, more detail is required to assess many of the proposed reforms, including the resourcing of the reforms.

The impact of regulatory reform on farmers and other agvet chemical users is not given detailed consideration in the Discussion Paper. The Association would like the objectives against which the reforms have been framed to include reference to agvet chemical users, and in particular to Australian farmers having access to chemicals which allow them to produce agricultural commodities using world-leading best practice.

In particular our Members need a regulatory 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, there needs to be clear and effective communication pathways between the APVMA and agvet chemical stakeholders.

It is understood that the Department of Agriculture, Fisheries and Forestry is in the early stages of developing reforms and that stakeholders will be invited to provide comment on draft legislation in mid 2011. By this time the Council of Australian Government (COAG) consultation Regulation Impact Statement (RIS) in regards to the establishment of a 'National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals' will have been published and stakeholders will be better placed to provide comment; the content of both papers will

be known and there will be greater understanding of how the two processes and proposed reforms will interact.

The Association is disappointed by the delays in publishing the RIS and that the Discussion Paper could not be assessed with knowledge of the content of the RIS.

The Association provides the following comments on the proposed reforms to legislation and regulations. Across all proposed reforms information about the associated costs needs to be made available for consideration and comment as there is the potential that they will be passed onto agvet chemical users. The proposed reforms have a public benefit component and it is therefore appropriate that public funding is made available for developing and implementing them.

1. IMPLEMENTING COMPLETE RISK FRAMEWORKS FOR AGVET CHEMICALS ASSESSMENT AND REVIEW

The Association supports a system in which risk is assessed using sound, evidence-based science and is transparent and consistent. It is proposed in the Discussion Paper that a number of risks in addition to environmental risks are considered in an overarching risk framework for agvet chemicals.

The inclusion of issues such as occupational health, residues, trade and efficacy is commendable. However the risk assessment framework needs to be practical, taking into account the ability of agvet chemical users to manage risk, not discourage chemical registrants from making registration applications and not threaten the access of farmers to a range of effective products. The continued access to agvet chemicals is critical to sustainable food and fibre production.

In developing the overarching risk framework for agvet chemicals the Association proposes that the APVMA invite the participation of industry experts to provide advice and feedback to ensure that it is practical for agvet chemical users.

2. IMPROVE THE QUALITY AND EFFICIENCY OF AGVET CHEMICAL ASSESSMENT AND REGISTRATION PROCESSES

While the Association is not a chemical registrant and is not directly involved in the assessment and registration processes, reforms which create a more efficient and timely registration system, avoiding unnecessary delays for industry will be of benefit to farmers.

To be international leaders in agricultural production (yields, quality, food safety, good environmental outcomes) and be competitive internationally Australian producers need to be served by a system that encourages applications for registration of new chemistry. Australian farming businesses often comment that new chemistry is available internationally but unavailable to them (even in small international markets which are comparable to Australia).

Agricultural industries value the efficacy and trade assessment components of applications. They safeguard our export markets and ensure that data is applicable to Australian production systems. The Discussion Paper states that the APVMA would not assess efficacy and trade components for applications where there is a low risk in excluding these assessments. While some examples are given of cases where an application might qualify for the exclusion of these assessments, the Discussion

Paper does not provide details as to how an application would qualify. The process for an application to qualify as low risk needs to be defined. Without more detail the Association is not supportive of efficacy and trade components being excluded from assessments.

While there may be instances where the risk from excluding efficacy and trade components from assessments is low, the Association has concerns if this was to occur. There are a number of biological products on the market, making claims of their ability to control pests and diseases and enhance soil biological activity. In many instances end users are unsure of their efficacy. The exclusion of efficacy data could also increase the risk of resistance developing if prescribed label rates are not appropriate.

In terms of assessment timeframes farming businesses in NSW and Australia need registration and review processes which are efficient and facilitate the timely introduction of new chemistry to Australia. The process and costs involved should not deter chemical registrants from seeking registration in Australia.

The details of the proposed optional accelerated assessment process are not outlined in the Discussion Paper. However, it should not redirect resources away from the existing assessment and registration processes and the focus should be on improving existing processes and certainty in timelines for chemical registrants.

The Association proposes that the input of farming representative and advisory bodies be requested to provide advice to an accelerated assessment process. Agricultural industries know if a particular product is needed and often have knowledge about whether it will be effective or not (e.g. from the use of the product overseas). They can give guidance as to whether a chemical registration warrants fast tracking. The costs of an accelerated process should not be fully borne by industry.

An APVMA process that is of vital importance to several Australian agricultural industries is the approval of minor use permits. Processes which improve the efficiency and timeliness of minor use permits would be most welcome. Additionally efficient and timely processes for approving emergency use permits are critical for agricultural industries. Permit applications and approval processes are not considered in the Discussion Paper. The Association would like the permit system to be considered as part of the reforms and any identified improvements implemented.

The registration process should include encouragement to chemical registrants to register uses rather than small agricultural industries having to rely on the minor use permit system. This would have the advantage of addressing the issues of varying control of use legislation between States and Territories where minor use permits are not required in some jurisdictions but required in others. The Association notes that this issue will also be addressed through the proposed 'National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals'.

3. ENHANCING THE AGVET CHEMICAL REVIEW ARRANGEMENTS

While the Association 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, it is concerned about the introduction of a new requirement for all agvet chemical approvals and registrations to be periodically reviewed.

The APVMA's existing chemical review program has the ability to initiate a review when new research or evidence has raised concerns about the use or safety of a particular chemical or product. The program also determines the scope of the review (e.g. environmental safety, occupational health and safety) by the specific concerns about the chemical. This ensures reviews are targeted to specific high risk chemicals and concerns.

The Association is concerned that the proposed review system may redirect resources and efforts away from high risk chemicals or products to those with a low risk. It is believed that the chemical review process is best managed through a targeted risk-based review program, which is currently provided through the existing chemical review program. More detail is required about the value the proposed review system adds to the existing program, the funding arrangements and how the increased workload will be managed by the APVMA.

Additional information about how the proposed review system compares with international review systems is required. If the data requirements of chemical registrants to meet contemporary health and safety standards in Australia are not in line with that required internationally Australian producers might be disadvantaged as chemical registrants will not be encouraged to seek re-registration of their products.

The cost of periodic reviews and the associated data collection and submission for all agvet chemical approvals and registrations are likely to be passed onto agvet chemical users. The Association considers this unacceptable and the costs of such a program should be borne by all beneficiaries, including the public.

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.

4. USING OVERSEAS ASSESSMENTS TO THEIR FULL EXTENT

The Association believes that the more effective use of overseas data, assessments and regulatory decisions by the APVMA as proposed should improve the efficiency of chemical assessments and registrations, providing benefit to Australian agricultural industries. This reform should be particularly beneficial in supporting minor use permit applications.

In using data generated overseas it is imperative that the Australian climate and environment and Australian farming systems are taken into consideration. Caution is required so that data is correctly applied and resulting registrations are safe and effective. In turn the Association does not want Australian agvet chemical users being denied access to chemicals which are safe and effective to use under Australian conditions.

To be able to fully support a change in legislation to encourage the APVMA and its regulatory partners to make more effective use of work conducted by comparable overseas agencies, which have applied a compatible approach, to the extent possible considering Australian conditions it is essential that more information is provided about how a “comparable overseas agency” and a “compatible approach” will be identified. A “compatible approach” is one which is in line with the APVMA’s registration process: “If the product works as intended and the scientific data confirms that when used as directed on the product label it will have no harmful or unintended effects on people, animals, the environment or international trade, the APVMA will register the product” (APVMA website).

5. ESTABLISHING AN INDEPENDENT SCIENCE PANEL

The Association supports a process by which the APVMA’s progress with reducing the backlog of reviews and improving the efficiency of assessments can be reviewed and recommended changes implemented. A process of continuous review and improvement will benefit agvet chemical users through more efficient and timely assessments, registrations and reviews.

As stated in the Discussion Paper the establishment of an independent science panel needs to be considered in conjunction with the proposal to replace the advisory board with expert advisor(s).

6. ENHANCING THE PROVISION OF EXPERT ADVICE

The proposal to remove the requirement of the APVMA to maintain an advisory board and replace it with expert advisor(s) is supported in principle by the Association as it will allow flexibility and give the CEO the ability to source advice from a range of experts with varying knowledge and experience.

The costs associated with an advisory board versus contracting individual expert advisor(s) and convening meetings with a mix of experts needs to be examined and made available for comment.

The Association requests that the process to identify and appoint expert advisor(s) be made clear and transparent. It is also requested that agvet chemical users be considered for expert roles. The Association considers they would bring considerable knowledge and expertise to discussions on issues such as spray drift. It is proposed that appropriate nominations for user expert advisors be requested from farming representative bodies and their agricultural chemical committees.

The use of external expert advisor(s) should not impact negatively on the knowledge and expertise within the APVMA.

7. IMPROVING LEGAL INTERACTION WITH THE APVMA

The Association does not have direct experience with the appeal process around APVMA recall and enforcement actions.

If unregistered products are available in Australia then a solution needs to be found. More information is required about the possible repercussions for users of unregistered and recalled products.

8. IMPROVING THE APVMA'S COMPLIANCE ENFORCEMENT CAPACITY

The Association supports in general the APVMA being provided with a modern graduated compliance activity. For further consideration more detail is required about the process of “tailoring penalty provisions to the degree and seriousness of the non-compliance”.

The separation of Commonwealth and State responsibilities for compliance are not made clear in the Discussion Paper. As outlined on page 6 of the Discussion Paper the Commonwealth is responsible for the regulation of agvet chemicals up the point of retail sale and beyond this point the regulation is the responsibility of the State and Territory Governments. Further information is required about the proposed changes to the APVMA's compliance enforcement capacity and how it may interact with the compliance activities related to the use of chemicals which are the responsibility of State and Territory Governments. Additionally it is noted that control of use is being considered as part of the proposed 'National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals'.

The Association proposes that communication channels between the APVMA and farming representative bodies be established so that farming representative bodies can be advised about upcoming compliance activity. Farming representative bodies can ask their members to be on the lookout for evidence of non-compliance for feedback to the APVMA. This will also assist with broader industry education on the agvet chemical regulatory regime and its operation.