



**National Farmers'**  
FEDERATION

24<sup>th</sup> February 2012

Agvet Chemicals  
Early Harvest and APVMA Reforms Team  
Agricultural Productivity Division  
Department of Agricultural, Fisheries and Forestry  
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**Comments on Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011**

The National Farmers Federation (NFF) was established in 1979 and is the peak national body representing farmers, and more broadly, agriculture across Australia. The NFF's membership comprises all of Australia's major agricultural commodities. Operating under a federated structure, individual farmers join their respective state farm organisation and/or national commodity council. NFF also has a number of associate members who participate in the agricultural supply chain. These organisations form the NFF.

The NFF is not involved in the registration of agricultural and veterinary chemicals, but represents a significant group of individuals who use agricultural and veterinary chemicals. For this reason the comments made by the NFF are not specifically related to the changes drafted in the amendments, but relate to the intent of the drafted changes. We ask that those who are responsible for drafting these amendments consider the impact and implications of the amendments for chemical users, and make changes where appropriate to avoid unintended consequences for chemicals users.

A Consultation Regulation Impact Statement (RIS) on a National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals was circulated in the first quarter of 2011, and included a discussion on a number of the concepts raised in the proposed amendments. In its response to the RIS the NFF raised a number of concerns and noted that the RIS did not provide a very clear discussion on the impact of costs or benefits from the various options. In the absence of a clear analysis of the costs and benefits of the proposed measures, the NFF continues to have concerns that the proposed changes will impact on the costs of chemicals and the availability of chemicals in the Australian market. It is important to highlight that agricultural and veterinary chemicals are fundamental tools which underpin the productivity and integrity of many farming systems. Agricultural industries must have access to a suite of chemicals for different purposes in order to manage their production systems. Many of the Australian agricultural industries compete in International markets, and it is important that Australian industries have access to the tools which will allow them to remain competitive in these markets. It is important that Australia's agricultural and veterinary chemical regulatory framework also look at processes and incentives to encourage new chemicals to be brought to the Australian market as they are developed and made available internationally. It needs to be recognised that while Australia exports significant quantities of agricultural produce we are a relatively small market for

agricultural chemicals. Effective mechanisms must be in place to allow Australia's agricultural industries to access the chemicals, particularly where there is a market or regulatory failure which means that chemical registrants do not have the incentive to register chemicals – particularly for 'minor-uses'. Fundamental in all of this is the need to ensure safe and effective chemicals continue to be available to chemical users while minimising the cost of regulation.

It is important that, if amendments to the legislation proceed, a comprehensive evaluation of their impact is made after implementation. The evaluation should focus on the impact of the amendments on chemical availability and cost, including a review of changes to the price of chemicals, the diversity of chemicals on the market as well as information on the number and types of chemicals for which registrations have been sought and subsequently completed.

#### Schedule 1 – Decision making using a risk based framework

NFF is not a chemical registrant and not in a position to comment on the detail of the proposed legislative changes. The use of transparent risk management frameworks which are based on scientific evidence to make assessments regarding risks to matters such as public health, occupational health and the environment are broadly supported. The amendments described require these frameworks to be taken into account, but how these frameworks are developed and used in practice will be an operational matter and it is not clear what oversight will be put in place to make sure that this is an efficient and effective process. The NFF would have concerns if there were delays in developing these frameworks or if the requirements of the frameworks introduced delays or additional costs to the application process.

The NFF has particular concern regarding the proposal to no longer undertake efficacy or trade risk assessments as part of its review process. No explanation has been provided as to how this arrangement would be applied. The NFF would suggest that if the Government does follow this path that there should be a clear decision framework to determine when these assessments do not apply, and where doubt or uncertainty exists then these assessments should be undertaken. It is the NFF's view that efficacy and trade risk assessments should be undertaken in all circumstances except where the chemical or veterinary medicine's use is not associated with a source of food or fibre in either domestic or international markets. The NFF raised similar concerns previously in its response to the RIS.

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

The NFF has made comments regarding changes to the management of the chemical portfolio in its response to the RIS and expressed significant concerns regarding the proposal to put in place a review process for registered chemicals. The NFF's concerns are that the proposed arrangements would reduce flexibility in the existing processes, impose additional costs as well as concerns that Australia may be establishing a system which is 'out of step' with the international standards. A practical concern is that registrants may not be prepared to support re-registration of chemicals for small markets or there may be market failures associated with supporting the review and re-registration of generic chemicals. The NFF also notes that the new chemical review and approvals arrangements are likely to increase the work associated with the registration of a chemical, and result in increased costs for registrants which will be passed onto chemical users. This is a very disappointing outcome for farmers, who are faced

with having to deal with these costs eating into returns. At a practical level, the loss of an approved chemical or removal of registration needs to be carefully managed and chemicals phased out of use to avoid creating stockpiles of chemicals that may result in environmental hazards or potential risks to human safety. The magnitude of the cost increase that will be associated with this process is also unclear.

**Schedule 3 – Improving quality and efficiency of assessment and registration processes**  
NFF is not a chemical registrant, and is not directly involved in the registration and assessment process. Costs incurred by registrants in the registration and assessment process and any inefficiencies in the process are passed onto farmers by chemical registrants in the form of increased chemical prices and delays in accessing newer chemicals. The costs of registration may also influence the decision to register a chemical in Australia by a chemical registrant. As a consequence of these considerations, the NFF would support the implementation of measures to improve the efficiency of the assessment and registration process. The NFF supports the requirement that efficacy data and trade risk should be considered as part of the registration process where a chemical is intended to be used in agricultural applications.

The NFF has a separate concern at the implications of these amendments for small agricultural industries which may be seeking to register chemicals for minor use applications. Cases exist where there is market failure and agricultural industries may approach the APVMA to register chemicals for minor uses. These agricultural industries, which are not traditional applicants, may fall foul of the new arrangements which would result in the loss of application fees and further delays in obtaining access to chemicals they require for the operation of their businesses. The current system provides flexibility which allows industries who are unfamiliar with the registration process to work with the APVMA. It is important that the viability of agricultural industries which rely on minor-use arrangements does not suffer as a consequence of these amendments.

#### **Schedule 4 – Enforcement**

The NFF recognises that chemical users, as well as the community more broadly, may benefit from improved compliance in the supply of chemicals. The amendments proposed are intended to strengthen the APVMA's compliance powers, but the operational and cost implications of an increased focus on compliance that need to be carefully considered. The RIS approved by the Office of Best Practice Regulation (reference 11523)<sup>1</sup> notes that the benefits from the improved compliance arrangements will flow to community and environmental stakeholders through increased confidence in the system and providing assurances relating to human health and safety and the environment. The RIS suggests that only a small benefit would be returned to the majority of approval holders and registrants as a result of the improved confidence in the regulatory system. Based on the flow of benefits it would appear that it is most appropriate for these compliance activities to be publically funded rather than cost recovered from industry.

#### **Schedule 5 – Data protection**

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<sup>1</sup> [http://www.daff.gov.au/data/assets/pdf\\_file/0008/2046167/agvet-ris-16nov11.pdf](http://www.daff.gov.au/data/assets/pdf_file/0008/2046167/agvet-ris-16nov11.pdf)

The NFF recognises that a careful balance needs to be struck on data protection arrangements. Data protection is required to protect the interests of registrants who are looking to recover the costs of developing and registering products. However, farmers also benefit from the availability of generic products which introduce competition into the market once data protection lapses on existing products. For this reason the NFF believes that it would be prudent to monitor the impact of the amendments on the chemical market, including the price and availability of chemical products.

**Schedule 6 – Arrangements for collecting levy**

The NFF supports arrangements that can improve transparency and administrative efficiency within Government, and in principle supports arrangements that would allow another Commonwealth agency to collect the APVMA's sales levy where this has the potential to reduce costs and improve administrative efficiency. It is important that in the short term savings made in this process are used to support and improve the APVMA's activities, and that ultimately the Government would look to pass savings back to chemical users through reductions in the sales levy.

Yours sincerely



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