



28 February 2018

Agvet Chemical Task Group  
Agvet Chemicals Branch  
Sustainable Agriculture, Fisheries & Forestry Division  
Department of Agriculture and Water Resources  
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Dear Agvet Chemical Task Group (ACTG),

The National Farmers' Federation (NFF) welcomes the opportunity to make a submission to the *Discussion Paper: Off-label Use Harmonisation Proposal*.

The NFF is the voice of Australian farmers and was established in 1979 as the national peak body representing farmers and, more broadly, agriculture across Australia. The NFF's membership comprises all of Australia's major agricultural commodities across the breadth and the length of the supply chain.

Off-label use currently differs dramatically between different jurisdictions, putting farmers operating in states and territories that have strict off-label use regulations at a competitive disadvantage. It is critical that any harmonisation of off-label use is comprehensive, and the mechanisms to implement, manage and monitor compliance is also 'harmonised' across jurisdictions.

A nationally harmonised approach to off-label use would be of benefit to the agricultural industry and would assist those who work and trade in various jurisdictions to ensure they were compliant with legislation on off-label use. The NFF agrees that off-label harmonisation would assist in compliance costs, reduce confusion over compliance and provide confidence with our international markets. We do not, however, support the proposed approach outlined in the discussion paper, particularly in relation to the proposed approaches for consistency in agricultural off-label uses.

The NFF has been supportive of past announcements of Government initiatives to harmonise off-label use between jurisdictions. NFF has been supportive of the AGMIN process, but have been disappointed with the lack of comprehensive reform in this area.

The production and distribution of agricultural chemicals and veterinary medicines (agvet chemicals) has changed dramatically in recent years, helping farmers to apply better chemicals in a more targeted manner. However, due to strict regulations around the registration of chemicals to the Australian market, many manufacturers refrain from registering those chemicals, or from adding additional off-label use. Consequently, it is

necessary to reform the current regulation of agvet chemicals without compromising the ability of the agricultural industry to respond to pests and diseases while maintaining the excellent biosecurity standards of Australian agricultural goods.

There is a significant need for flexibility in off-label and minor use permits particularly for niche markets (such as lavender, ginseng and saffron). Availability of alternative pest and disease management tools is critical if the industry is to meet the production standards and stiff competition expected in these niche markets. Currently, the cost of developing the necessary documentation to meet regulatory requirements for minor use permits is prohibitive for many of these niche markets, and manufacturing companies are limited in the financial returns that may be gained by accessing niche markets in Australia.

It is important that the harmonisation of off-label use doesn't impinge on the agricultural industries access to chemicals. The NFF recommends that the ACTG engage in specific consultation with the agricultural industry to provide clarification around some of the details outlined in the proposal. It is important into the future that off-label use supports a continued minor use program (which the NFF believes should be extended and intensified). It is also imperative that there is a mechanism that allows for the transition of permits to on-labels, while ensuring that off-label use doesn't deter chemical companies looking to invest in the Australian market.

The NFF recognises that there are initiatives in place in attempt to remedy the lack of incentives under the current Federal mandatory regulations for minor use permits. The NFF is particularly supportive of the work of the Agricultural Chemical Access Priorities Forum, which has resulted in the APVMA, government and industry working together to establish crop groupings to simplify the registration of minor use chemicals and through migration permits to labels. This approach provides a legal regulated pathway for producers to gain access to chemicals for minor use.

In relation to the proposal to limit the use of application equipment that is not listed on the APVMA approved label, the NFF believes that further consultation with the agricultural industry regarding the cascade model is needed as there is some confusion in regards to how equipment will be 'graded'. The NFF agrees that there is adequate legislation to protect the environment and workplace safety without introducing another layer of regulatory burden.

The NFF is concerned that the proposal contains a condition of off-label use as being only for domestic use. The reality is that, in some cases, the eventual market may not be known to the producer. This element of the proposal is problematic, although could be avoided by obtaining a minor use permit which would enable an MRL to be established.

There are a range of new technological solutions for delivering agvet chemicals in use in a number of countries, and it will only be a matter of time before Australian farmers adopt these new technologies on a broader scale. A number of these technologies (drones, swarm bots etc.) pose a considerably reduced risk to worker safety and the environment due to their autonomy and precision in monitoring environments and making analytical decisions in delivering chemicals. It is unclear from the discussion paper how these new innovative technologies for delivering agvet chemicals will be 'graded' in relation to equipment listed on APVMA labels.

There needs to be greater incentive given to manufacturers of products to include more off-label use. Currently there is no incentive for manufacturers to list off-label use as the costs of acquiring this data is prohibitive. The NFF understands that the APVMA is looking at ways to incentivise manufactures listing more off-label use on labels, but this is still some way off. In the interim, the minor use permit system should be utilised more effectively to harmonise off-label use.

Farmers need the flexibility to be able to adapt relatively quickly to changes in the environment that may require chemical intervention, and minor permits and off-label use are one of the most effective tools they can use. Non-financial incentives should be examined such as fee waivers, transferrable rights (i.e. where a registrant earns a credit for an expedited review which can be transferred to another registration application) and longer exclusivity periods, to incentivise more manufacturers to list off-label use.

Rapid response to new, unforeseen biosecurity issues is critical for agricultural productivity and protecting trade. The NFF considers that prevention, early detection, rapid response and working collaboratively across both industry and government is required to protect Australia's 'clean, green' image. Major biosecurity incidents affect not only the environment and primary producers, they have the potential to affect all of Australia (including, for example, the tourism sector), and thus require a swift response. Harmonisation of off-label chemical use will be of significant benefit to the agricultural industry and Australia more broadly by providing the industry with tools to maintain healthy environments. If you require any additional information regarding this submission, please contact Mark Harvey-Sutton (Manager, Rural Affairs) on 02 6269 5666.

Yours sincerely



**TONY MAHAR**  
**Chief Executive Officer**