



26 February 2021

Ken Matthews AO
Chair
Independent Review Panel: Review of the agvet chemical regulatory system
CANBERRA ACT 2601

Dear Mr Mathews,

RE: Submission to Draft Report of the Independent Review of the Agvet Chemicals Regulatory System

The National Farmers' Federation (NFF) welcomes the opportunity to provide a submission to Independent Panel's Draft Report of the Independent Review of the Agvet Chemicals Regulatory System.

Should you require any further information in relation to this submission, please contact Mike Darby, General Manager Rural Affairs at the National Farmers' Federation, on 02 6269 5666 or mdarby@nff.org.au.

Yours sincerely,

TONY MAHAR
Chief Executive Officer



**National
Farmers
Federation**

National Farmers' Federation

Response to the Draft Report of the Independent Review of the Agvet Chemicals System

Prepared by Mike Darby

26 February 2021

NFF Member Organisations





**National
Farmers
Federation**

The National Farmers' Federation (NFF) is the voice of Australian farmers.

The NFF 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.

Operating under a federated structure, individual farmers join their respective state farm organisation and/or national commodity council. These organisations form the NFF.

The NFF represents Australian agriculture on national and foreign policy issues including workplace relations, trade and natural resource management. Our members complement this work through the delivery of direct 'grass roots' member services as well as state-based policy and commodity-specific interests.

Statistics on Australian Agriculture

Australian agriculture makes an important contribution to Australia's social, economic and environmental fabric.

Social >

There are approximately 85,000 farm businesses in Australia, 99 per cent of which are wholly Australian owned and operated.

Economic >

In 2018-19, the agricultural sector, at farm-gate, contributed 1.9 per cent to Australia's total Gross Domestic Product (GDP). The gross value of Australian agriculture in 2018-19 was \$62.208 billion. This is expected to fall to \$59.353 billion in 2019-20 due primarily to the drought. The NFF's ambition is to achieve \$100 billion in farm gate output by 2030.

Workplace >

The agriculture, forestry and fishing sector employ approximately 318,600 people, including full time (239,100) and part time employees (79,500).

Seasonal conditions affect the sector's capacity to employ. Permanent employment is the main form of employment in the sector, but more than 26 per cent of the employed workforce is casual.

Environmental >

Australian farmers are environmental stewards, owning, managing and caring for 51 per cent of Australia's land mass. Farmers are at the frontline of delivering environmental outcomes on behalf of the Australian community, with 7.4 million hectares of agricultural land set aside by Australian farmers purely for conservation/protection purposes.

In 1989, the National Farmers' Federation, together with the Australian Conservation Foundation, was pivotal in ensuring that the emerging Landcare movement became a national programme with bipartisan support

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Executive Summary

The National Farmers' Federation (NFF) welcomes the opportunity to provide comment on the Draft Report of the Independent Review of the Agvet Chemicals Framework (Draft Report). We thank the Independent Review Panel (the panel) for its engagement with the NFF and its member organisations throughout the consultation process.

Access to safe, effective, and innovative technologies – such as agvet chemicals – underpins our agricultural productivity, sustainability and competitiveness, and is a priority for the farm sector. Indeed, access to world leading technologies will be critical to achieving the sector's ambition of \$100 billion in farm gate output by 2030. The NFF's 2030 Roadmap recognises this, and calls for a fit-for-purpose regulatory environment that manages risk without hindering access to safe technologies. In this context, we see this review as a valuable opportunity to modernise and streamline the agvet chemical regulatory system so that it is fit for the future.

The NFF strongly supports the independence and scientific rigour of our national regulator for agvet chemicals, the APVMA, and this must be maintained. However, we recognise considerable opportunity for reform to improve efficiency, encourage innovation and investment, and optimise access to agvet chemicals for Australian farmers.

Australian farmers need a system of chemical regulation and registration that facilitates the introduction of new chemicals onto the Australian market in a timely and cost-efficient manner, without compromising the health and safety of people, animals and crops, the environment and trade. The NFF is supportive of the government's commitment to reforming the regulation of agvet chemicals and reforms that support improved efficiency and effectiveness of the regulatory environment are welcomed by the NFF.

The NFF understands that, in undertaking this review, the panel has:

- Assessed the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme,
- considered what the goals of Australian agvet chemical regulation should be considered the current and future requirements of Australia's regulatory framework for agvet chemicals, and
- provided recommendations for reform of the regulatory framework to increase the value of Australian agriculture.

With respect to the Draft Report, the NFF would like to both congratulate and caution the panel on the scale of the proposed changes. We also strongly encourage the NFF and industry continue to be consulted as the process moves forward.

Comments on the specific proposals put forward the consultation paper are detailed in the following pages.

Introduction

On 4 September 2020, the NFF made a submission in response to the release of the *“Issues Paper – review of the Agvet chemicals regulatory system: future reform opportunities”*. That submission provided comment on a range of issues identified by the NFF and its members. The key points the NFF made at that time included:

- The proposed system objectives are a good start, but amendments are needed including to highlight the importance of supporting trade and market access.
- A risk-based approach to regulatory assessment is strongly supported.
- Harmonisation of control of use is a priority, and careful consideration must be given to the management of issues such as off-label use.
- Shared responsibility is an important mechanism for achieving regulatory efficiencies, and there are opportunities for expanding this approach.
- Education and capacity building are efficient means of managing unintentional non-compliance and should be supported.
- There are risks associated with the proposal to remove some plant protection and animal health products from the regulatory system.
- Agricultural chemicals and veterinary medicines should continue to be regulated under the same framework.
- A benefits test should not be a condition of product registration, but the regulator should be enabled to prioritise applications for assessment.
- Further discussion is needed about a nationally coordinated monitoring program for domestic produce and the environment.
- The regulator and the department should play greater roles in educating and reassuring the community regarding the regulator’s purpose and processes.
- Efficacy assessment should remain a requirement of registration, including GM products.
- Further consideration should be given to how the regulator can best use international data and assessments while also managing risk.
- The system should incentivise registrants to invest in new use patterns and provide growers with access to a wider range of agvet chemicals.
- Chemical reviews should be risk-based and triggered by new information.
- The introduction of electronic (smart) labelling should be prioritised, while ensuring that labelling meets the needs of a range of end users.
- Expanding the use of third-party assessors, with appropriate safeguards in place, has merit.
- The regulator must be sustainably funded, through an appropriate mix of cost-recovery and appropriation.

It must be said from the outset, the compact timing of these consultations and the deadlines for response, combined with the sheer number of recommendations, 139 in total, has provided numerous challenges for the NFF providing feedback to this draft report. Despite the short consultation period, since the release of the Draft Report, the NFF has been able to participate in a number of consultative meetings and pull together short notice meetings to undertake consultations with our members and other industry stakeholders.

Part 1 – The NFF welcomes regulatory reform

The NFF welcomes the opportunity for regulatory reform that the Independent Review of the Agvet Chemicals Regulatory System (the Review) presents, and the opportunity to provide an industry perspective to the recommendations provided in the Draft Report.

Access to technologies depends not only on the right regulatory framework, but also on the right investment environment. Due to the small size of the Australian market, Australian farmers can have difficulties accessing agvet chemicals or uses that are available to overseas competitors. This is a particular issue for smaller industries and the risks presented by emerging pests and diseases.

The NFF strongly supports the Australian Government's improved access to agricultural and veterinary chemicals initiative, which helps to address this market failure and generate a significant return on investment. We encourage the panel to consider how national regulatory settings can assist with addressing the minor use issue, and incentivising investment in the Australian market.

A central consideration for the panel should be ensuring that the regulatory system creates certainty for investors in research and development into the next generation of crop protection and animal health technologies. The regulatory environment plays an important role in the development and adoption of innovative technologies and practices. This review is a critical opportunity to optimise and encourage innovation and support Australian agriculture's international competitiveness.

The NFF notes the limited success that has been realised through the current approach to achieve harmonisation, and therefore supports policy that aims to improve harmonisation of control of use. Differing state specific use patterns and instructions for certain products creates a number of issues for end users, which the panel has described in the issues paper. Assessing products by region where there are genuine specific environmental or biological considerations (beyond what already occurs through the APVMA's assessment processes) may be beneficial, however would need to be carefully managed to ensure it does not lead to confusing or overly complicated label instructions.

Despite the significant opportunity that this review presents in terms of reforming the national agvet chemical system in Australia, the NFF has identified a number of concerns. These concerns, identified in consultation with our members, need to be addressed if the government is to move forward with the recommendations outlined in the Draft Report.

- The NFF welcomes the opportunity for the regulatory reform that the Review presents.
- Despite the significant opportunity that this review presents in terms of reforming the national agvet chem system in Australia, the NFF has identified a number of concerns.
- NFF congratulates and cautions the panel on the scale of the proposed changes.

Part 2 – Adequate resourcing is key to maintaining public trust in our production systems

Public trust in Australia’s agvet chemical registration and control of use systems is critical to the continued use of these products in Australian food and fibre production systems. Recently highlighted concerns around the use of glyphosate, if not successfully satisfied, have the potential to undermine the productive capability of much the worlds agricultural production for which the global population relies. The NFF supports the sentiment in the Draft Report that notes:

“Increasing interest in chemical use and its potential impacts on the community is focussing attention on the quality and the integrity of global regulatory systems, including Australia. Social media and other mechanisms for rapid communication provide means to publicly highlight any real or perceived lapses in safe practice or shortcomings in government regulatory oversight.”

The NFF welcomes recommendations that aim to nationally harmonise the control of use. The current system does not optimise national harmonisation of control of use, relying on Commonwealth legislation and then seven states and territories to monitor and enforce. Recommendations 7 through to 17 seek to address harmonisation by extending Commonwealth powers to the entire control of use system. These recommendations are concerning to the NFF and our members.

Adequate resourcing of our national system is key to maintaining public trust in our production systems. The proposal to effectively replace the current role of the states in respect to control of use, raises the question of resourcing the Office of the Commissioner to an equivalent level to those currently held by the combined state governments and their respective government departments.

The NFF notes that good resourcing will require personnel, expertise and funding – much of which is currently provided by state governments. The NFF is concerned by the lack of implementation or rollout planning. Further concerns regarding funding and the issue of cost recovery are dealt with later in this submission.

The panel has noted considerable resources at the Commonwealth’s disposal. However, consultations with NFF members (and other stakeholders) have revealed serious concerns that much of the Commonwealth’s resources are currently overcommitted in other areas of governance and operations. Consultations with members and stakeholders have revealed a high level of confidence, both on farm and in communities, in the existing APVMA registration system. The NFF do not support significant changes to this system.

- The regulatory system must be adequately resourced in order to maintain public trust.
- The proposed creation of the Office of the Commissioner will require significant resourcing (both in personnel and expertise) to match the current system housed within the states.
- NFF requests a stocktake of “current system versus proposed system” to be included in the implementation strategy.

Part 3 – Managing costs is key to maintaining Australia’s agricultural competitiveness

Australian farmers will need to improve their competitiveness if we are to achieve our shared vision of becoming a \$100 Billion industry by 2030. To this end, the regulatory costs experienced by our farmers simply cannot be allowed to increase above current levels.

Australian agricultural producers are among the most efficient in the world. However, regulatory costs that are passed to farmers, cannot be passed on to export markets due to competition from our competitors on the global market. The NFF agrees with the panel that:

"Improving access safe and effective pesticide and veterinary medicine products will be important to assist Australian Primary producers to successfully compete with their international counterparts."

Australia’s regulatory systems, like our farming communities, must be globally competitive, and only add costs where equivalent value can be added. Further, increased costs must be equitably apportioned between industry, government and the broader community.

The NFF notes recommendations 120 through to 135 propose full cost recovery of certain regulatory activities, including the cost of control of use, presumably by the proposed Office of the Commissioner. The NFF is concerned that recommendations to cost recover major parts of the regulatory system, including the newly created Office of the Commissioner, would see much of the costs passed down to chemical users, and therefore farmers.

The NFF is unable to fully support any drastic changes to the functioning and funding of the agvet chemical system without full costing of the proposed system so that it may be compared with the costs imposed by the existing system.

- Australian farmers are the end of the line receivers of regulatory costs imposed by Government and passed down through the production chain.
- The NFF does not support the imposition of higher regulatory costs on farmers, either directly or indirectly.
- The creation of the Office of the Commissioner has the potential to increase regulatory costs for Australian farmers and, in turn, diminish their international competitiveness.
- The NFF requests a published full costing of the proposed system.

Part 4 – Future management of residues

The NFF supports the use of systems that keeps chemical residues within reasonable and legal levels. As previously stated in Chapter 2 of this submission, public trust in Australia's agvet chemical registration and control of use systems are critical to the continued use of these products in Australian food and fibre production systems.

The NFF agrees with the previous issues paper's assertion that *"there is a growing awareness amongst the community about the potential for chemical residues to be found in food ..."*. The NFF encourages further consultation for nationally coordinated monitoring of domestic produce and the environment.

The NFF notes that recommendations 22 through to 27 relate to improved residue monitoring, particularly in commodities with a domestic trade focus. Currently the National Residue Survey only monitors residues in a small number of commodities, which are exported. There is limited domestic produce monitoring currently undertaken. The states and territories are responsible for monitoring chemical residues, however, there is no consistent methodology applied across jurisdictions and currently only three states (QLD, VIC and WA) undertake monitoring.

If the Commonwealth were to assume the monitoring functions currently undertaken by the state, the National Residue Survey would likely need to be expanded. The scope and purpose of any national monitoring program would need to be clearly defined and appropriately designed and funded, to minimise regulatory burden and costs, maximise benefits and mitigate associated risks. Any new national monitoring program would also need to incorporate effective trace-back processes so that any issues that are identified can be sourced, investigated, and remedied. Without such processes in place the identification of residues may aggravate community concerns.

The NFF would be supportive of the expansion of the National Residue Survey, as part of overall reform. However, given the importance of this system, a separate review and public consultation process would be required - over and above the current review process.

NFF members have raised concerns surrounding the proposed use of industry Quality Assurance (QA) systems to ensure residue compliance as part of control of use. Current QA programs rely on pre-market assessment to formulate their risk management plans. If products are approved via a licensing scheme with no data provided though the international pathway to registration by referral, QA schemes will have nothing to assess. Additionally, costs are likely to increase here and the burden of the increase will be borne by growers.

Questions around equivalency between industry QA schemes, the need for auditing and the potential for increased costs would need to be considered, as part of rollout or implementation planning.

- The NFF supports the use of systems that maintain residues at, or below, allowable levels.
- If the Commonwealth is to assume the responsibilities of the states for residue testing, the current National Residue Survey would likely need expanding.
- A separate process of review and consultation will be required to expand the NRS to ensure it is appropriately designed and funded.

Part 5 – The creation of a licencing scheme

Australian farmers can have difficulties accessing particular agvet chemicals or uses that are available to overseas competitors, due to the small size of the Australian market. This is a particular issue for smaller industries and for emerging pests and diseases. The NFF strongly supports improved access to agricultural and veterinary chemicals. In our previous submission we encouraged the panel to consider how national regulatory settings can assist with addressing the minor use issue.

Recommendations 81 through to 90 would effectively create a licencing scheme to allow for safe and effective use of products registered by certain pre-approved and trusted international regulators. Groups other than importers and manufacturers could apply for such licences and would have the sole distribution right and the responsibility for use.

Users of regulated agvet chemical products must have confidence that these products are proven to be effective before being approved for use in Australia. This raises the question of how to include the assessment of unique Australian circumstances, which would not have been considered by a foreign regulator. This is not an insignificant challenge, and if not adequately addressed could present risks to human, animal and environmental health and compromise our trade status. For this reason, the NFF would recommend significant caution in pursuing this approach.

The NFF supports the concerns raised by NFF member organisation Cotton Australia surrounding the removal of GM crops from the scope of products regulated. Registration requirement for stewardship, reporting of efficacy and non-compliance to the regulator is an important element to the success of the registration of GM products. While there may be scope to remove duplication between the OGTR and the APVMA, a system that is able to govern the stewardship of GM crops at a landscape level will be crucial to the success of all GM crops in the future. We recommend the panel refer to the feedback submitted by Cotton Australia for more detail on these concerns.

Harmonisation of control of use is a priority, and careful consideration must be given to the management of issues such as off-label use. There are a range of views on the off-label system currently available in Victoria, which can provide greater range of access that is important to growers, but ultimately means that the end user accepts liability. The benefits and risks of this approach need to be carefully considered when designing future systems.

- Australian farmers have difficulty accessing particular agvet chemicals or uses that are available to overseas competitors.
- Recommendation 81 raises the question of how to include the assessment of unique Australian circumstances, which would not have been considered by a foreign regulator.
- The NFF does not support removing "efficacy" from the scope of regulating GM products.
- Careful consideration must be given to the management of issues such as off-label use.

Part 6 – The need for implementation planning

The Draft Report, with its 139 recommendations, and remarkably short consultation period, has both surprised and concerned many of NFF's members. Concerns from members around the planning process, implementation and rollout have been common throughout the consultation period. The Draft Report, particularly around the proposal for the creation of an Office of the Commissioner, would have benefited greatly from the provision of an implementation plan.

Common questions around the creation of the Office of the Commissioner taking over control of use from the states include *"will the states be required to refer their powers to the Commonwealth and what will happen if they don't? Will we end up with parallel systems?"*

The NFF requests that the panel engage in an implementation planning process which allows for stakeholder consultation. A detailed proposed implementation plan should be developed and provided to stakeholders, including indications of timeframes and consultation opportunities.

It is critical that the panel's final report is implementable and engenders the confidence of governments, regulators, the regulated community, livestock producers, supply chain producers, export market participants, consumers and other stakeholders.

- The NFF has a number of concerns around the implementation of the 139 recommendations of the Draft Report.
- Common questions include *"What will happen if the states choose not to refer their current responsibilities to the commonwealth? Could we end up with parallel systems?"*
- The NFF requests that the panel engage in an implementation planning process which allows for stakeholder consultation.

Conclusion and opportunities for further review

The NFF reiterates its appreciation of the opportunity to provide comment on the Draft Report for this important national review of Australia's regulatory system for agvet chemicals. Again, we thank the Panel for its engagement with the NFF and its member organisations throughout the consultation process.

Given the ambitious nature of the Draft Report, and its 139 recommendations, much consideration will have to be given to the planning process moving forward. The NFF notes that consultations with the Panel revealed it could take as long as a decade to implement all of the recommendations, allowing for continued consultation as we move forward.

The NFF considers that more consultation will be required in order to effectively implement the panel's recommendations and that this consultation would be best be hard-wired into the implementation planning process.