



**National Farmers' Federation**  
**Submission to the Agricultural and Veterinary**  
**Chemicals Legislation Amendment Regulations 2018**

21 February 2019

# NFF Member Organisations



Australian Chicken Growers' Council Ltd



TREES | WOOD | PAPER



CANEGROWERS





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

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

## **Social >**

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There are approximately 88,000 farm businesses in Australia, 99 per cent of which are wholly Australian owned and operated.

## **Economic >**

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In 2017-18, the agricultural sector, at farm-gate, contributed 2.4 per cent to Australia's total Gross Domestic Product (GDP). The gross value of Australian farm production in 2017-18 is estimated to have reached \$60.1 billion.

## **Workplace >**

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The agriculture, forestry and fishing sector employs approximately 323,000 people, including full time (236,700) and part time employees (84,300).

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 >**

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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**

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The National Farmers' Federation (NFF) welcomes the opportunity to comment on the Department of Agriculture and Water Resources' proposed changes to timeshift applications and other measures, and to support operational efficiency (Agricultural and Veterinary Chemicals Regulations 2018).

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. NFF is supportive of the government's commitment to reforming the regulation of agricultural and veterinary (agvet) chemicals. Reforms that support improved efficiency and effectiveness of the regulatory environment are welcomed by the NFF.

Several measures in this package of regulations relate to provisions in the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill and the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill, both of which are currently before the Australian Parliament. The NFF was consulted during the development of these Bills, and in our public submissions acknowledged that the measures proposed would support improvements in the agvet chemical regulation system. The related regulatory changes being proposed by the department will support the realisation of these improvements pending the passage of the primary legislation. We would welcome the opportunity to be consulted should there be any amendments during the legislative process.

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

## **Proposal 1: Timeshift applications**

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The NFF supports the proposal to expand the types of applications that may be assessed using a timeshift application, recognising that this would enable some products to enter the market with fewer delays. The NFF understands the proposed changes restrict the types of applications to which a timeshift approach would apply to those where the additional administrative burden created is most likely to be offset by the benefits of the flexibility provided by a timeshift approach. Consideration could be given to further expanding the availability of timeshift in the future, once the impact of the proposed changes has been assessed.

NFF also supports the related proposal to amend the fee schedule in Schedule 7 to reflect the extended range of timeshift applications, and ensure that fees better reflect regulatory effort. We would welcome the opportunity to be consulted on any additional charges that may be applied to timeshift applications during the review of the APVMA Cost Recovery Implementation Statement.

## **Proposal 2: Ministerial orders**

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The NFF is supportive of changes to the Agricultural and Veterinary Chemicals Codes Regulations 1995 (Code Regulations) to provide a single authority for ministerial orders – this would streamline, and may provide greater visibility of, the scope of ministerial orders. A ministerial order provides a simpler alternative to regulation, which can allow greater responsiveness and flexibility, which is appropriate in some circumstances.

Currently a minister may only make an order in regards to standards for chemical products, and tests for the analysis of samples of substances or mixtures of substances. We understand that the proposed changes allow for the minister to make an order on any matter that may be prescribed in the regulations that does not involve prescribing a penalty. It is important that thorough consideration is given to the types of additional matters that would be prescribed under this authority, should this represent an expansion of the scope of ministerial powers. While ministerial orders are legislative instruments and are subject to parliamentary scrutiny and disallowance, there is no legislated requirement for public consultation. We would encourage the department to adopt a best practice approach and commit to continuing to consult on these matters, as per the current regulatory approach. Ministerial orders must be backed by scientific rigour, and not triggered solely by publicised community concern. A ministerial order would be appropriate for the examples given in the consultation paper, however it is not clear whether this list captures the full scope of the proposed powers.

## **Proposal 3: Chemical product declaration**

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The NFF fully supports the proposed changes to chemical product declarations, which relate to substances that are low risk in nature and are adequately regulated under other laws controlling chemical use. Specifically, the NFF agrees that carbon-dioxide and nitrogen when used as fumigants, and citronella oil (other than as an insect repellent for use on human beings) be added to the regulations as substances or mixtures declared not to be agricultural chemical products. The

NFF also agrees that sheep branding substances do not need to be regulated as veterinary chemical products, and should be removed from Schedule 3AA of the Code Regulations.

In addition, the NFF recommends that the department consider incorporating the following categories of low-risk substances into the regulations as substances that should not be regulated as agricultural or veterinary chemicals:

- Selected or novel endophytic fungi. For example in perennial ryegrass (see [https://www.dpi.nsw.gov.au/\\_data/assets/pdf\\_file/0006/109995/endophytes-of-perennial-ryegrass-and-tall-fescue.pdf](https://www.dpi.nsw.gov.au/_data/assets/pdf_file/0006/109995/endophytes-of-perennial-ryegrass-and-tall-fescue.pdf)).
- Endemic pathogens and microorganisms, unless combined with a carrier or adjuvant and promoted as an effective bio-herbicide product. Consideration should be given to provision of a clear demarcation between registration requirements for a formulated bio-herbicide or bio-pesticide versus the collection and spread of naturally-occurring, endemic pathogens.

We would be happy to discuss this matter further.

#### **Proposal 4: Notifiable variations and prescribed variations**

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The NFF is supportive of the proposal to simplify the process for making notifiable variations and prescribed variations, by repealing regulations 19AE and 19AF of the Code Regulations and relying solely on the APVMA to make legislative instruments for these variations. We understand that these sorts of variations are used for minor matters where minimal or no assessment by the APVMA is required (e.g. a change to the name of a manufacturer of a chemical product).

The NFF agrees that consolidating the variations will avoid unnecessary and confusing duplication where both regulations and APVMA legislative instruments can be used concurrently to deal with the same or similar matters.

#### **Proposal 5: Hormonal growth promotants**

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The European Union (EU) is an important market for many Australian beef and veal producers and there are significant opportunities to expand our reach into this market, including in the context of the EU Free Trade Agreement currently under negotiation. Australia's continued access to the EU market for beef and veal products largely depends on our ability to provide assurance that these products have not been treated with hormonal growth promotants (HGPs). Several other trading partners (including China) also require that Australian meat and meat products are produced from HGP-free animals.

HGPs remain an important part of beef production across Northern Australia where pasture quality declines during the dry season and cattle growth needs to meet market specifications. HGPs cause no harm to the animal being implanted and research has shown meat treated with HGPs is safe for human consumption. Australian producers purchasing and using HGPs must



comply with a range of regulatory requirements, including identifying treated animals with an ear mark, and maintaining purchase and use records.

We understand that the penalty measures being proposed relate to the supply of HGPs. The NFF strongly supports measures to modernise the regulation of HGPs and to provide the APVMA with proportionate options for responding to non-compliance. We support the proposal to increase the penalty from 10 units to 30 or 50 penalty units, and it is appropriate for these to be civil penalties. As noted in the consultation paper, it is important that the penalty for contravening the requirements set out in the Code are commensurate with the potential impact – which in this case is significant. The NFF also supports the provision in the regulations for infringement notices to be issued, as an alternative to prosecution or litigation. Effective regulation would be better supported by access to a graduated set of tools to address non-compliance.

The NFF supports in principle the proposal to provide the APVMA with the ability to take administrative action to deal with non-compliance with the supply and record-keeping requirements for HGPs. While the consultation paper does not explicitly suggest that there are systemic issues with non-compliance, the range of measures proposed suggests that the APVMA's existing powers do not provide a sufficient deterrent. It is critical that our trading partners have confidence in Australia's national monitoring system for HGPs.

### **Proposal 6: Section 88 exemption (allowing advertising)**

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The NFF is supportive of the proposed changes, which we understand will address an anomaly in the agvet regulations that restricts the advertising of legitimate substances, including those authorised under a permit. We note that this restriction could have unintended consequences such as prohibiting the issuing of a notice about a product authorised under a permit during a biosecurity emergency, or undermining supply of a legitimate product approved under a permit (which could include minor use permits).

### **Proposal 7: Restricted information**

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The proposed amendments present a practical approach to address an irregularity between the Agvet Code and the Code Regulations in the definition of the term 'protected information', which affects how this information can be used. The introduction of the term 'restricted information' in Part 1 of Schedule 6 of the Code Regulations, and the clarification that the constraints on the use of 'restricted information' only apply if the APVMA would have to use the information to register a proposed product may provide greater certainty to applicants.

### **Proposal 8: Assessment Periods and Fees (active approval as part of registration)**

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The NFF supports the proposed changes to reduce the red tape associated with approving active constituents in certain circumstances, where the approval can efficiently be sought in connection with the application for registration of a chemical product. We understand the changes would also

enable companies to seek a single active constituent approval (in specified circumstances) when seeking to register a range of new products with the same active constituent. These changes are supported, as they would reduce the regulatory burden on applicants and the APVMA, without compromising the rigour of the assessment process.

The NFF supports the simplification and streamlining of applications of chemical products of similar nature as this will provide an incentive for the development and registration of chemicals where there might not be a large domestic commercial market. The NFF also sees that it is important to ensure that testing of all products (no matter how similar to another approved product) is rigorous enough to prevent unsafe or ‘sub-par’ chemical products from reaching the market.

### **Proposal 9: Consequential and other amendments**

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The NFF supports these minor amendments, which we understand are largely administrative in nature, including making minor corrections, addressing inconsistencies and updating references to provisions in other legislation.

### **Proposal 10: Transitional provisions**

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The proposal that all application provisions relating to amendments of the Agvet Code be kept together and inserted in the Code Regulations as a new division is understood to be consistent with current drafting conventions, and is viewed as a practical measure.

## **Additional undrafted regulation changes**

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### **Proposal 11: Voluntary recalls**

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The NFF is supportive of a more transparent and proactive recall process, and endorsed the approach proposed in the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill whereby an approval form is completed to advise the APVMA of the recall. It is appropriate that the APVMA is always informed where a product is being voluntarily recalled because it does not meet statutory or labelling criteria, or is not a registered chemical product. These sorts of incidents can present serious risks to industry, and there is therefore also a need for a process by which farmers can be notified quickly and efficiently if the products they have purchased have been recalled. The NFF has previously raised concerns about the risks to industry created by the existing arrangements for voluntary recalls, which place considerable onus on supply chains to ensure all parties are notified of potential contaminations.

In some circumstances, such as where a product has not been supplied to a retail premises or a product user, it would be appropriate that the APVMA is exempt from the requirement to publish a notice.

The NFF supports the proposal to grant the APVMA the power to issue an infringement notice instead of only being able to pursue criminal or civil proceeding in court. It is appropriate that the

APVMA has a graduated suite of compliance options available, in order to respond to non-compliance in a proportionate manner.

### **Proposal 12: Determining applications**

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The NFF supported the proposal in the Streamlining Regulation Bill to provide the APVMA and industry with greater flexibility in regards to providing certain (limited) types of information during the assessment period for an application. The understanding at that time was that this would relate to information of a non-technical nature, which would lead to some efficiencies within the application process (i.e. provision of this information would no longer trigger an extension of the assessment period). We understand that the government has been asked to consider extending this provision to include some data requiring technical assessment (such as stability data). The proposed extension to the availability of timeshift applications (Proposal 1) should address this issue to some degree, and we note that use of a timeshift mechanism would also give the APVMA forewarning and an ability to plan and allocate resources according to an agreed project plan.

For information requiring technical assessment, we understand the intention is to take a strict approach to the type of data that can be provided through this mechanism, so as not to have the effect of undoing the 2014 changes to the Agvet Code. This approach is supported in principle by the NFF, noting the specific input being sought (direct experience with seeking registration of date-controlled products requiring real-time stability data) is a matter for product registrants.

The NFF supports the proposed types of information that may be provided without issuing a notice or triggering an extension – noting that these are minor information deficiencies that would not realistically add to the assessment time required by the APVMA.

### **Proposal 13: Improving application quality**

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The NFF supports the proposal for the APVMA to be able to introduce fees to assess information required by a notice under section 159 of the Agvet Code when dealing with deficient applications. It is unfair on industry members who present high quality applications to pay for other industry member's inadequate applications through the re-allocation of APVMA's time and resources. Charging applicants a fee at an hourly rate is a sensible approach, which will best ensure that the additional costs to applicants reflects the additional effort required by the APVMA. The provision to allow any decision to charge a fee to be a reviewable decision is appropriate. All in all this will improve the quality of applications received and reduce the administrative burden on the APVMA.

## **Changes to support Operational Efficiency Bill measures**

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### **Proposal 14: Annual returns reporting and false misleading information**

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The NFF agrees that the APVMA should maintain its ability to issue infringement notices for contravening annual returns reporting requirements. Having access to a range of compliance tools is important and will allow a proportionate response to non-compliance.

The NFF also supports for the APVMA to issue infringement notices for alleged contraventions of section 69ER of the Administration Act and section 146 of the Agvet Code, where a person commits an offence if that person knowingly gives false or misleading information or produces false or misleading documents. It is important that these offences are taken seriously, as they have the potential to compromise the integrity of the regulator.

### **Conclusion**

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The NFF commends the government on their commitment to reforming the national system of agvet chemical regulation, and would support the proposals set out in the Agricultural and Veterinary Chemicals Legislation Amendment Regulations 2018, with respect to the comments that have been made in this submission.

The NFF would be available to expand on any of the issues referred to in this submission. In the first instance queries should be directed to:

Adrienne Ryan (General Manager, Rural Affairs), National Farmers' Federation

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