



20 December 2018

Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
Canberra ACT 2600

Via email: rrat.sen@aph.gov.au

Dear Committee Secretariat

RE: Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018

The National Farmers' Federation (NFF) is pleased to respond to the Senate Standing Committees on Rural and Regional Affairs and Transport's Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

The NFF refers the Committee to its initial submission (**attachment A**) on the exposure draft of the Bill earlier this year. The NFF notes that there are other matters relating to the Australian Pesticides and Veterinary Medicines Authority (APVMA) that are being addressed through different processes.

The NFF considers the proposed Bill a reasonable and functional process to deliver minor improvements to efficiency and our position as per the initial submission stands.

For further information, please contact Warwick Ragg, General Manager NRM

Yours sincerely

TONY MAHAR
Chief Executive Officer



National Farmers' Federation

Submission to the Consultation on Streamlining Regulation of Agricultural and Veterinary Chemicals

NFF Member Organisations





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.

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Executive Summary

The National Farmers' Federation (NFF) welcomes the opportunity to comment on the Department of Agriculture and Water Resources Consultation on Streamlining Regulation of Agricultural and Veterinary Chemicals.

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. The NFF is supportive of the government's commitment to reforming agricultural and veterinary chemical legislation and is also supportive of the government pursuing reforms to the Code Act (including the Agvet Code). Any reforms that provide measures that will make the regulatory environment more efficient and effective are welcomed by the NFF.

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.

Policy reforms should also be underpinned with sufficient incentives to bring newer and safer chemicals to market, particularly in cases where there may not be a commercial incentive for manufacturers due to the small Australian market.

Proposal 1 – Provisional registration or variation with conditions for efficacy (provisional registration of chemical products)

Provide the APVMA with discretion to provisionally register products, or provisionally register new uses of existing chemical products (vary product registrations), by allowing information about the efficacy of a product to be provided after registration, as a condition of registration.

The NFF welcomes any move by the APVMA to encourage registration of innovative or novel products to be supplied to the Australian market, and believe this measure will go some way to encouraging registration of innovative uses of existing products.

It will be critical that the APVMA develop guidelines to inform stakeholders and assessors about the circumstances around a product being considered for provisional (or varied) registration.

The NFF is supportive of streamlined efficacy assessments and believe that they may be suitable for some low risk products. The NFF understand that the APVMA is already progressing in this direction with the support of industry.

Proposed provisional registration (for a limited time) is also supported by the NFF, as is limitations on the types of products that can be eligible for provisional registration (eg restricted chemical products). There is a need however, for supplementary information from the APVMA on when provisional registrations would be considered, as well as the timeframes being proposed to supply the additional efficacy information to confirm the product meets the criteria. The NFF is supportive of the provision of an additional two years of registration in special circumstances, and believe this will provide some flexibility where issues arise that are outside the control of the applicant.

The NFF would propose that an additional safeguard to provisional registration would include the applicant having not had a registration cancelled for contravening conditions of registration or for providing false or misleading information. Additionally, the NFF would assert that provisional registration be ‘offered’ at the APVMA’s discretion following consultation with the applicant.

Provision registration needs to consider practical labelling requirements for the user, reseller and registrant. Any subsequent update to labels after efficacy data is provided to APVMA needs to be cost-neutral and easy to adopt throughout the supply chain from product manufacture, reseller to end user storage. In relation to labelling of provisionally registered products, the NFF recommends that the product is listed on the APVMA website.

Proposal 2 – An accreditation scheme for assessors in the future (*accreditation of assessors*)

Provide for a disallowable APVMA legislative instrument to prescribe an accreditation scheme for assessors in the future, including charges for accreditation, and provide for sanctions for contravening conditions of accreditation.

The NFF supports the proposed amendments to the Agvet Code to provide for a legislative instrument to prescribe an accreditation scheme for assessors into the future. However, NFF note the need for rigour in the quality of external assessors and their assessments and the importance of consultation with industry on details of the accreditation scheme prior to its introduction.

The NFF concurs that offences for non-compliance pertaining to conditions of accreditation be extended to overseas persons or agencies. The NFF would suggest that stronger assurance is needed in prosecution of these types of offences, and proposes that any offences of this nature committed by an overseas person or agency have significant penalties associated with them.

Proposal 3 – Prescribed approvals and registrations (*approval and registration for active constituents, chemical products or labels*)

Provide for prescribed approvals and registrations to simplify the approval of active constituents and labels, and the registration of certain products (to be set out in regulations or other instruments).

The NFF is supportive of proposals to further streamline the approval of active constituents and labels and registering chemical products. Any measures to make the approval process more efficient and cost effective is welcomed by the NFF, particularly when the application is for a low or medium risk product.

NFF endorses the approach taken in regards to disqualifying criteria, and believe that the proposed approach is consistent with the intention of proposal 3, and will better enable the APVMA to concentrate its resources where most appropriate. To this end, the NFF believes that the APVMA should have the ability to cancel an approval or registration if the application is found to have knowingly presented false, misleading or inaccurate information for a prescribed approval or registration.

The NFF would welcome being engaged in the proposed consultation process of the development of the legislative instrument or regulations.

Proposal 4 – Data protection incentives for certain uses of chemical products (*limits on use of information*)

Provide for extensions to limitation and protection periods (to be set out in regulations or other instruments) as an incentive for registration holders to include certain uses of chemical products on labels and reduce the need for permits.

It is critical that incentives are provided to those who introduce new products and additional uses into the Australian market. Further flexibility and return on investment for registrants needs to be built into the system, especially for extended uses of generic products, improved withholding periods and generating additional water quality or residue level data.

The NFF is supportive of the amendment of the Agvet Code to allow for regulation to reflect changes to the existing limitation and protection periods.

Proposal 5 – Prescribe certain information that can be taken into account if provided during an assessment (*information to be taken into account in determining applications*)

Provide the APVMA and industry with more flexibility to deal with certain prescribed types of information (to be set out in regulations or other instruments) given while the APVMA is determining an application.

The NFF is supportive of the proposal 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 NFF also concurs that this information should be of a non-technical nature and be clearly prescribed in legislation. The NFF believe that this proposed measure will lead to some efficiencies within the application process as it will allow for additional non-technical information be provided during assessment and reduce the time required to process applications.

Proposal 6 – Provide for computerised decision-making (*computerised decision-making*)

Modernise the Agvet Code by providing for the APVMA to use computerised decision-making.

The use of computerised decision-making as part of the approval and registration process is supported by the NFF. We believe that this proposed measure has the potential to introduced considerable efficiencies within the APVMA by eliminating the need for staff to assess the administrative details of the approval or registration process.

The NFF is supportive of computerised decision-making for processes that are largely administrative, and believe that it is appropriate that there is a suitable transition period to allow the APVMA to develop the necessary systems. This will ensure that there is accuracy and consistency in the computer decisions-making process.

The NFF endorses the proposed approach of allowing for the APVMA to substitute a decision for an incorrect decision made by a computer program, and believe that this proposed measure will enable the APVMA to effectively address any anomalies in the computer decision-making process.

Proposal 7 – Improve the transparency of voluntary recalls (*voluntary recalls*)

Improving transparency about recalls of agvet chemicals by requiring persons to inform the APVMA when they are undertaking certain voluntary recalls and requiring the APVMA to publish such recalls.

The NFF is supportive of a more transparent recall process, and endorses the proposed approach where by an approval form is completed to advise the APVMA of the recall. The NFF believe that it is appropriate that the APVMA publish recall information.

Products can be recalled from the market for a variety of reasons, the NFF would contest that the proposed measure be restricted to situations where the reasons for recall are based on distribution of an unregistered chemical product or compliance with the statutory criteria.

Recent incidents involving the possibility of contaminated herbicides and pesticides has highlighted the need for a process for farmers to be notified quickly and effectively that their purchased products may have been contaminated. Currently, a voluntary recall process applies when a potential contamination is deemed not to have public safety implications. This places considerable onus on supply chains to ensure all parties are notified of potential contaminations.

There is potential for a simple notification system, either via text or email, to be developed to be utilised in the event of either a voluntary or mandatory recall. The benefit of such a system is its targeted approach to those already within supply chains, its efficiency and utilisation of digital agriculture. Ideally such a system would be administered by the APVMA as the industry regulator. However, the APVMA must be adequately resourced to implement such a system.

Proposal 8 – Require relevant information to be provided in relation to label approvals and variations (*notification of new information*)

Ensure that obligations to provide relevant information apply to holders of label approvals, and applicants for both label approvals and variations to approvals or registrations; as they do in relation to active constituent approvals and product registrations.

The NFF is supportive of more consistency in agvet chemical labelling, and concur that this proposed measure will ensure alignment of requirements for label approvals and variations with those for active constituent approvals, product registrations, permits and licenses. The NFF believe that this measure will provide some administrative efficiency within the APVMA as it will provide an avenue to facilitate post-market compliance.

Proposal 9 – Standards for registered chemical product constituents (*definition of registered chemical product*)

Reduce the regulatory burden on industry and the APVMA by allowing defined variations to the constituents in chemical products.

The agricultural sector supports a framework which ensures chemicals are safe and effective, while ensuring the compliance burden is proportional to the potential risk posed by a product. The NFF support the proposal to allow defined variations to the constituents in chemical products. The NFF is supportive of reasonable (safe) variations in constituents arising from the manufacturing process, and that these have a ‘default’ concentration range that comply with the concentration range in the register. The NFF is also comfortable with the proposed approaches if a concentration is not specified in the register or no order has been made by the minister.

The NFF believe that this measure will result in these technical details being updated more efficiently as standards develop. The NFF would welcome any opportunity to be engaged in further consultation at the appropriate time regarding this proposed measure.

Proposal 10 – Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval
(suspension or cancellation of approval or registration for provision of false or misleading information)

Include more comprehensive grounds for suspending or cancelling approvals or registrations where false or misleading information is provided, including in a variation application or an application for label approval.

The NFF is supportive of the proposed approach to suspend or cancel active constituent approvals and product registrations where false or misleading information is provided.

Proposal 11 – Addressing an inconsistency in label particulars *(supply of registered chemical products with unapproved label)*

Address an inconsistency in the Agvet Code by clarifying what information must be included on a label.

Consistency in labels is critical for Agvet chemical users, and as such, the NFF is supportive of the measure to require product labels to only contain relevant particulars that are required to be included, and believe that this measure will go some way to address inconsistency in the way labelling is regulated. The NFF has raised concerns in the past regarding inconsistency in product labelling requirements, and while this measure will address some of those concerns, there is still work to be done on making labels consistent and more user-friendly. The overall size of labels, durability and font size of active constituent(s), etc need to be considered across a range of product containers. NFF has provided previous feedback to the department about the need for user-friendly label protocols.

Proposal 12 – Improving dealings with suspended approvals and registrations (*variation of approval or registration during suspension*)

Introduce practical measures to deal with suspended approvals and registrations, to address the reason for a suspension and to allow holders to request a suspension.

There are administrative efficiencies to be gained in the proposal to allow for variations to the relevant particulars and conditions for a product registration that is suspended. The NFF is supportive of measures that allow applicants to address issues that result in suspension and return the product to the market in a more efficient way.

Proposal 13 – Address anomalies in matters that can be prescribed for the statutory criteria (*safety, efficacy, trade and labelling criteria*)

Address anomalies in the Agvet Code in relation to prescribing matters for the labelling criteria, and for overseas trials and experiments (including international assessments and data) for the safety, efficacy, trade and labelling criteria.

The NFF does not oppose the proposal to allow for the regulations to prescribe matters the APVMA must have regard to for the purpose of being satisfied that a label meets the labelling criteria.

The NFF have strongly supported in the past the approach that the APVMA is currently operationally delivering, in regard to international standards, assessments and data.

The NFF supports the provision that the APVMA would retain discretion over how it uses this material and its decision-making role in registrations and approvals be preserved. It is important that the APVMA is able to continue to take international data into consideration when approving registrations. The NFF agrees that it is unnecessary to introduce a legislative requirement currently, as the APVMA is already maximising the use of international standards, assessments and data.

Proposal 14 – Simplifying APVMA corporate reporting requirements (*annual operational plans*)

Simplify the APVMA's corporate reporting requirements by removing the need for the APVMA to develop and seek approval of an annual operational plan in addition to the corporate plan required annually under the *Public Governance, Performance and Accountability Act 2013*.

The NFF does not oppose the simplification of the APVMA corporate reporting requirements, and believe that this measure will provide administrative efficiencies due to reduced duplication in reporting.

Proposal 15 – Align the 2014 legislation review with the overarching review of agvet chemical legislation (*other amendments*)

Align the review measures in agvet chemical legislation.

The NFF endorses the approach of aligning the timing of the review (under section 4 of the Amendment Act) with the review that is required under section 72 of the Administration Act. The NFF is of the view that aligning these processes will avoid duplication and unnecessary administrative costs.

Proposal 16 – Make minor and machinery changes to the Administration Act and Agvet Code (*other amendments*)

Make minor and technical amendments to the Administration Act and the Agvet Code, including removing redundant and unnecessary provisions.

The NFF is supportive of the measure to update the Agvet Code and Agvet Code Regulations and concur that by removing the redundant and unnecessary provisions within the Act it will provide better clarity on measures of the Act.

Proposal 17 – Other Amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016 (*other amendments*)

Incorporate agvet chemical-related measures currently in the Agriculture and Water Resources Legislation Amendment Bill 2016, into the Streamlining Regulation Bill.

It is important that there is consistency in legislation, as such, the NFF is supportive of the implementation of the Agriculture and Water Resources Legislation Amendment Bill 2016 (the Omnibus Bill). The NFF is hopeful that this measure will provide small efficiency gains in APVMA administrative operations as it will eliminate the need for the APVMA to notify FSANZ of unnecessarily detailed information (after commencement).

Conclusion

The NFF commends the Government on their commitment to this process and would support passage of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2018 through Parliament. NFF member organisations will be providing further commentary on the details of the Bill and we would encourage you to consider these submissions.

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:

Warwick Ragg (General Manager, NRM), National Farmers' Federation