



Submission on Streamlining Regulation of Agricultural and Veterinary Chemicals

Section A: General information

Purpose of this form For individuals and organisations to provide submissions on streamlining regulation of agricultural and veterinary chemicals.

Use this form to provide a submission or to write a long-form response.
You can also attach a separate response.

Before applying See [Agriculture and Veterinary Chemicals Legislation Amendment \(Streamlining Regulation\) Bill 2018](#).

Closing date 22 August 2018

To complete this form Save the document to your computer.

Your submission must include a completed and signed submission form
 where relevant, supporting information from organisations, written on their official letterhead.

Post or email (preferred) your submission Agvet Chemicals
Sustainable Agriculture, Fisheries & Forestry Division
Department of Agriculture and Water Resources
GPO Box 858
Canberra ACT 2601
Email agvetreform@agriculture.gov.au

Section B: Applicant

- 1 Organisation name:** The Western Australian Farmers Federation (Inc)
- 2 Contact address:** PO Box 556, Belmont, WA 6984

3 Contact person

Given name(s): Jessica Wallace

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Email: grains@wafarmers.org.au

Section C: Confidentiality

4 Is all of your submission confidential?

No

5 Is part of your submission confidential?

No

Section D: Publication of submissions on the department website

Unless you request otherwise, the department will publish your name, organisation and the title of your submission on its website. Your contact information will not be made available.

6 Do you agree to your submission being made publicly available?

Yes

7 Do you agree to your name and state/territory being listed?

Yes

8 Do you agree to the department contacting you about your submission if required?

Yes

Section E: Submission type

9 What type of submission are you making? (select one box only)

Response to key topics in the draft report → Go to section F

Section F: Response to key topics in the consultation paper

WAFarmers supports and endorses the submission contributions from Grain Producers Australia (GPA) and Australian Medical Association (AMA), and acknowledges the contributions made to the WAFarmers submission by Dr Enoch Bergman (Swan Veterinary Practice Esperance WA).



WAFARMERS

Submission to the:
Consultation on Streamlining Regulation of
Agricultural and Veterinary Chemicals
22nd August 2018

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Background

The Western Australian Farmers Federation Inc. (WAFarmers) is the State's largest and most influential rural advocacy and service organisation.

Founded in 1912, WAFarmers boasts a membership of over 3,200 primary production businesses including grain growers, meat and wool producers, horticulturalists, dairy farmers, commercial egg producers and beekeepers.

Collectively our members are major contributors to the \$8.2 billion gross value of production that agriculture in its various forms contributes annually to Western Australia's economy.

Additionally, through differing forms of land tenure, our members own, control and capably manage many millions of hectares of the State's land mass and as such are responsible for maintaining the productive capacity and environmental wellbeing of that land and the animals that graze it. Agriculture was the largest contributor to national GDP growth in 2016-17, and is the fastest growing industry, particularly driven by the grains and livestock industries.

Executive Summary

WAFarmers welcomes the opportunity to comment on the consultation document and would like to offer the following comments for consideration.

In terms of the proposals for AgVet chemicals, WAFarmers do not in principle have any major apprehensions with the proposed approaches however we are concerned about whether the changes will result in significant improvements to our regulatory environment.

The proposed changes appear to give the APVMA more latitude and strength in dealing with organisations that contravene the process, which is important in protecting our industry. Most of the procedural substance regarding accelerating the registration process' specifically, the computerised decision making processes, is excellent. There are some strong measures that may provide advantages to large multi-nationals over local or generic companies, which need some consideration. Another concern, is the inadequate distinction between Agri-Chemical and Vet-Chemical products of which vet chemicals already has excellent regulation, oversight and enforcement (through veterinary deregistration).

In regard to products that already exist within Australia, gaining access to use it on "new" animal (e.g. using Dectomax Injectable (labelled for cattle and swine) for sheep is currently achievable through individual producers working with their veterinarian), veterinarians are allowed wide extra label prescribing rights for the benefit of their clients, however they are also professionally and financially liable for outcomes.

The proposed legislative change will assist the livestock industry to make some products that exist in Australia more accessible, however when a pathway to market already exists, there may not be much incentive for companies to pursue label changes primarily due to the substantial investment required. Furthermore, the Australian grains industry would be significantly disadvantaged by being subject to unwarranted re-registration of off-label chemical actives. This unnecessary regulatory process has the potential to create significant additional costs for growers and to deter beneficial

commercial investment in this area generally.

WAFarmers Responses to the Questions in Context to the Submission Paper

10. Comment on provisional registration of chemical products

WAFarmers supports simplifying conditional registration as proposed, however the current proposed regulatory reform does not address key areas specific to Australian residue trials and the resulting data. This area significantly impacts barriers to chemical registration in Australia.

11. Comment on accreditation of assessors

WAFarmers supports the proposed approach to the reforms, which provide great options for recourse to the APVMA to manage accredited assessors, especially in light of the potential for greater numbers and types of assessors that may be necessary due to the changes in the provisional registration scheme. WAFarmers also supports the outsourcing of “third-party” assessors, which are APVMA approved. WAFarmers also suggests a formalised review process is implemented whereby assessors are rotated through to ensure integrity is upheld within the system.

12. Comment on approval and registration for prescribed active constituents, products and labels

WAFarmers supports the proposed reform for prescribed approval and registration. Changes to the regulations capable of simplifying the approval and registration of prescribed active constituents, products, and labels would be welcomed by WAFarmers.

13. Comment on data protection incentives (limits on use of information)

Protecting entities which take on the risk of either innovating new products or conducting the appropriate trial work to demonstrate efficacy within Australia at face value is both fair and just. WAFarmers supports the proposed changes in principal, however, the proposed changes may benefit from some reworking to allow pragmatic interpretation so as to prevent larger, better funded organisations such as multi-nationals from securing exclusivity of product registration claims where they intend to utilise that exclusivity to either restrict access or worse refrain from marketing products viewed as competitive to their existing products. If a product is well established in its use overseas for instance, and a number of generic products exist, it would seem inappropriate to restrict access to a single organisation within Australia.

14. Comment on information to be taken into account in determining applications

WAFarmers supports the proposed changes and encourages the reform to avoid unnecessary delay and “red-tape” in the chemical approval process. The proposed changes should both improve the quality of submissions and provide recourse for additional supporting information for most submissions.

15. Comment on computerised decision-making

WAFarmers strongly supports the proposal to modernise the AgVet Code through modern technology and more up-to-date decision-making resources, such as computerised chemical labelling systems, whereby electronic labels are made available for registered chemical product. This will provide an easier, more efficient process, and ensure that grain growers have access to up-to-date information that can be integrated into their on-farm electronic technologies. WAFarmers

believes the implementation of computerised decision-making processes by the APVMA is a benefit to industry and should be implemented within the streamlining process.

16. Comment on voluntary recalls

WAFarmers supports the voluntary recall of AgVet chemicals where this is considered necessary and encourages the APVMA to publish any such recalls. This published information will allow growers to make better informed decisions with regards to their on-farm chemical programs. WAFarmers also understands that not all voluntary recalls warrant a public notice via the APVMA. Accordingly, WAFarmers encourages retaining some degree of flexibility for minor risks and suggests that, before a recall is published, the APVMA investigates the nature of the recall. In doing this, it would ensure the regulatory process is not unnecessarily burdened.

17. Comment on standards for registered chemical products

WAFarmers supports the proposed reforms, so long as all label approvals, and variations to existing approvals or new registrations, are labelled clearly for consumer use. Access to new information is viewed as beneficial to all parties involved, and WAFarmers continues to support improved standards to chemical labelling.

18. Comment on suspensions or cancellation of approvals and registrations for providing false or misleading information

WAFarmers supports the reform in minimising the provision of misleading information in relation to the AgVet Code. Clarity is required in relation to the APVMA's ability to intervene with suspension, cancellation, approval or registration. WAFarmers supports the reform and encourages clear transparency.

It is important to ensure that the APVMA is permitted to suspend registrations or product variation permits when false information is provided. This ensures that stakeholders are provided accurate information and ensures safe handling of approved products.

19. Comment on addressing an inconsistency in label particulars (supply with unapproved label)

WAFarmers continues to support the reform with regards to labelling particulars. Greater transparency and clarification surrounding approval holders and product marketers is important, and WAFarmers supports a clearer understanding of product labelling. It is important to ensure that the APVMA suspends registrations or product variation permits when false information is provided. Ensuring stakeholders provide accurate information and that information is not omitted is paramount to ensuring access to safe, efficacious products.

20. Comment on variation of approval or registration during suspension

WAFarmers is concerned with the proposed changes to the variation of approval or registration during suspension. Whilst pragmatic responses to a chemical suspension may be warranted under a particular circumstance, not all 'problems' or suspensions pose the same associated risk. This reform has the ability to significantly weaken product availability, even after a suspension has been lifted. Registrants have a responsibility to ensure product availability. A penalty must be implemented to

ensure prolonged suspensions do not occur. WAFarmers supports greater flexibility in dealing with suspended applications.

21. Comment on prescribing matters for the statutory criteria

WAFarmers does not support the change in legislation on prescribing matters that can be prescribed for the statutory criteria. Unnecessary “red-tape” should not be further embedded into our own regulatory framework, when the APVMA is already utilising international standards. Creating unnecessary ties to overseas legislation could adversely impact on Australian production. Should an international “trigger” occur, sparking an international regulatory review, Australia will be significantly restricted. Creating greater flexibility in dealing with suspended applications is viewed as a very positive goal.

22. Comment on removing the need for an annual operational plan

WAFarmers does not oppose the proposal to simplify the APVMA’s reporting requirements, WAFarmers does, however, believe the annual operational plan provides much needed industry transparency of the APVMA’s operational plans. Thus WAFarmers supports the continuation of the annual plan. The proposed changes should allow greater flexibility in the utilisation of appropriate overseas data at the discretion of the APVMA.

23. Comment on aligning the 2014 legislation review with the current review of AgVet chemical legislation

WAFarmers does not support the alignment of the 2014 legislation review with the current review of Ag Vet chemical legislation. WAFarmers supports more strategic legislative measures and insists these measures should cover greater issues such as improved data innovations, improved labelling systems and the continued adoption of new technologies. These key areas need to be addressed and reviewed. Currently, the regulatory framework does not address these key individual areas.

Section H: Applicant declaration

To be completed by the person listed in section B of this application.

I understand that:

- the Australian Government reserves the right to refuse to publish submissions, or parts of submissions, that contain offensive language, potentially defamatory material or copyright infringing material
- a request may be made under the *Freedom of Information Act 1982* for a submission marked confidential to be made available. Such requests will be determined in accordance with provisions under that Act
- if I provide personal information about an individual other than myself, I must make that person aware of the privacy notice in section I of this form and draw their attention to the department's privacy policy.

Signatures: D.P. Young, J. Slade

Date: 21/08/2018

Full name: DUNCAN YOUNG & DAVID SLADE

Section I: Privacy notice

'Personal information' means information or an opinion about an identified individual, or an individual who is reasonably identifiable.

The collection of personal information by the Department of Agriculture and Water Resources in relation to this submission is for the purposes of gathering information on the Exposure Draft of the Agricultural and Veterinary Chemicals (Operational Efficiency) Bill and related purposes. If you do not provide this information, the department will be unable to contact you to discuss your submission.

Under the *Freedom of Information Act 1982*, submissions marked confidential may be made available. Such requests will be determined in accordance with provisions under that Act.

Personal information may be published on the department's website, disclosed to other Australian agencies, persons or organisations where necessary for these purposes, provided the disclosure is consistent with relevant laws, in particular the *Privacy Act 1988*. Your personal information will be used and stored in accordance with the Privacy Principles.

See the department's Privacy Policy to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933.