



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 (if applicable) Grain Producers Australia _____

2 Contact address

Postal address PO Box 3517 _____

Suburb/town/city MANUKA _____ State/territory ACT _____ Postcode 2603 _____

3 Contact person

Given name(s) Andrew_____ Family name Weidemann_____

Work phone _____ Mobile phone 0428 504 544_____

Email andrew.weidemann@grainproducers.com.au_____

Section C: Confidentiality

4 Is all of your submission confidential?

No ☒

Yes ☐ Clearly mark the submission 'In confidence'

5 Is part of your submission confidential?

No ☒

Yes ☐ Clearly mark the relevant section(s) 'In confidence'

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?

No ☐ Go to question 8

Yes ☒ Go to question 7

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

No ☐

Yes ☒

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

No ☐

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

☐ Long-form response to the whole draft report → Go to section G

☒ Separate response in an attached document → Go to section H

Section F: Response to key topics in the consultation paper

Support your answers with references.

10 Comment on provisional registration of chemical products

11 Comment on accreditation of assessors

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

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

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

15 Comment on computerised decision-making

16 Comment on voluntary recalls

17 Comment on notification of new information

18 Comment on standards for registered chemical products

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

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

21 Comment on variation of approval or registration during suspension

22 Comment on prescribing matters for the statutory criteria

23 Comment on removing the need for an annual operational plan

24 Comment on aligning the 2014 legislation review with the current review of agvet chemical legislation

25 Comment on other minor and machinery changes to the Agvet Code and the Administration Act

**26 Comment on other amendments from the Agriculture and Water Resources Legislation
Amendment Bill 2016**

**27 Comment on other minor and machinery changes to the Agvet Code and the Administration
Act**

28 Other comments. This could include additional information or relevant issues to be raised.

→ Go to section H

Section G: Long-form response to the consultation paper

29 Support your response with references. Attach additional sheets if necessary.



SUBMISSION

GPA response to the consultation on Agricultural and Veterinary Chemicals Legislation Amendment exposure draft (Streamlining Regulation) Bill 2018

Addressed to:

Streamlining Regulation of
Agricultural
and Veterinary Chemicals
AgVet Chemicals Branch
Department of Agriculture and
Water Resources
GPO Box 858
Canberra ACT 2601

22 August 2018

GPA response to the consultation on Agricultural and Veterinary Chemicals Legislation Amendment exposure draft (Streamlining Regulation) Bill 2018

Thank you for the opportunity for Grain Producers Australia (GPA) to provide a response to the **Agricultural and Veterinary Chemicals Legislation Amendment exposure draft (Streamlining Regulation) Bill 2018**¹.

The GPA submission is made on behalf of all our members including the State Farming Organisations. In some cases State Farming Organisations such as WA Farmers will be putting in a separate submission to more clearly articulate state based concerns. In other cases such as for the Victorian Farmers Federation, they would like DAWR to recognise their viewpoint and concerns have been submitted as part of the GPA submission and they have therefore chosen not to make a separate submission.

As detailed in the 2014 and 2017 GPA submissions regarding Agvet chemicals regulatory reform, the outcomes for community and industry that need to be achieved through policy and legislative reform include;

- Increased National and foreign investment in Australia
- Increased agricultural profitability and sustainability
- Increased delivery of a diverse range of foods to a multicultural community
- Increase productivity and scale of industries contributing to GDP and balance of trade
- Improving safety to community, environment and trade.

Potential options for addressing increased investment in Australia have been identified which include;

- Improved prioritisation
- New incentives for investment
- Co-investment partnerships
- Increased clarity on benefits and return on investment
- Regulation co-equivalence opportunity
- Clarity of roles for commercial companies, RDCs and regulators
- Regulation reforms.

The proposed regulatory reforms detailed in the Agricultural and Veterinary Chemicals Legislation Amendment exposure draft (Streamlining Regulation) Bill 2018 only address a small number of the issues identified, or in some cases created, through previous rounds of legislative reforms. There is clearly a need for further legislative reform to deliver technology access outcomes for Australian agriculture including grain growers.

There is an urgent need for the chemical industry to embrace digital agriculture and automation technologies and the legislation must embrace these 21st century technologies and encourage the consideration of these systems by the APVMA. There is also an urgent need for reforms to enable electronic labels and for these changes to be reflected in state control of use legislation.

¹ <http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/streamlining/public-consultation>

Executive Summary

GPA provides the following overview of our comments on the exposure draft. Further clarification of the rationale behind these positions is contained within the body of the submission.

GPA partly supports the proposed approach on reforms for provisional registration of chemical products, however this should be extended to chemical residues. GPA in previous submissions has proposed a provisional registration program of chemical products. GPA has proposed the establishment of a provisional and/or conditional registration system with fee payment deferral options based on agro-ecological co-equivalence and same use in crops/animals overseas

GPA partly supports the proposed approach to reforms on accreditation of assessors, however limitations of liability need to be recognised. GPA recognises that there has been an APVMA pilot study using external assessors. GPA considers that there is significant opportunity for implementation of third party APVMA approved certifiers rather than current APVMA monopoly.

GPA partly supports the proposed approach to reforms for prescribed approvals and registrations.

Regarding Data Protection mechanisms **the GPA supports the government in engaging in a discussion on potential incentives to support increased AgVet investment into Australia** to provide the tools and production capacity for industry to remain internationally competitive.

GPA does not support the proposed legislative initiative reforms as proposed. Reforms to the legislation do not link the proposed incentives to industry need or priorities. The proposal to limit extension of the protection period only if the application to vary an existing registration is made at least three years before the limitation or protection period for the information associated with the existing registration expires, will result in companies delaying decisions for support of minor crops and where market failure exists.

GPA supports the proposed approach to reforms for prescribed approvals and registrations. Reforms that speed up the evaluation process and avoid unnecessary delays for new chemical approval should be implemented in legislation.

GPA supports the proposed approach to reforms to modernise the Agvet Code by providing for the APVMA to use computerised decision-making. There is an urgent need for the chemical industry to transform from current 19th century paper based systems into a 21st century smart digital agriculture system.

GPA supports 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.

GPA supports the reforms ensuring that obligations to allow 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.

GPA supports the reform to enable label holders to make reasonable variations, reducing the regulatory burden on industry and the APVMA by allowing defined variations to the constituents in chemical products.

GPA supports the reform to address the anomaly in the AgVet Code whereby the APVMA is unable to suspend or cancel an approval or registration where false or misleading information is given.

GPA supports the reforms addressing an inconsistency in label particulars. GPA agrees with the Department that legislative amendment is required to clarify the nominated agent and the holder of approval, as opposed to the marketer of the product.

GPA is concerned with the proposed changes to the reform on variation of approval or registration during suspension. GPA understands that in a number of cases there is a need for a more pragmatic mechanism to vary a suspended chemical product registration

GPA does not support the proposed change in legislation relating to matters that can be prescribed for the statutory criteria (safety, efficacy, trade and labelling criteria).

GPA does not support the removal of the requirement of an annual operational plan in addition to the corporate plan required annually under the *Public Governance, Performance and Accountability Act 2013*. GPA believes that the publication of the annual operational plan provides transparency of its operational plans, which will be additionally supported by the proposed re-establishment of the APVMA board.

GPA does not support the planned alignment of review measures in AgVet chemical legislation.

Background: Grain Producers Australia

Grain Producers Australia (GPA) represents Australia's broadacre, grain, pulse and oilseed producers at the national level. Grain Producers Australia works to foster a strong, innovative, profitable, globally competitive and environmentally sustainable Australian grains industry. Representing 5200 farm businesses, it strives to represent Australian grain farmers nationally and internationally in their contribution to sustainable development and society.

Working with its members – state farm organisations and farmers across the grain production area of Australia - GPA advocates for sound outcomes that deliver a positive commercial result. GPA is a not-for-profit company limited by guarantee. It is governed by a board, elected by its members.

The objectives of GPA are to:

- Provide a strong, independent, national advocate for grain producers based on a rigorous and transparent policy development process.
- Engage all sectors of the Australian grains industry to ensure operation of the most efficient and profitable grain supply chain.
- Facilitate a strategic approach to research, development and extension intended to deliver sound commercial outcomes from industry research.

The GPA policy council, is strategically focused on three pillars of economic development, social responsibility and environmental management.

Our policy council includes representatives from State Farm Organisations including:

- Agforce Grains
- Grain Producers SA
- NSW Farmers Association
- Victorian Farmers' Federation Grains Group
- Tasmanian Farmers and Graziers Association
- WA Farmers
- WA Grains Group

GPA manages the biosecurity program for the grains industry through Plant Health Australia and is a joint Representative Organisation (RO) responsible for overseeing the performance of the Grains Research and Development Corporation (GRDC).

GPA and AgVet chemicals

GPA has been engaged for many years in cross industry discussion in relation to increasing market failure of commercial investment in agricultural pesticides and veterinary medicines (AgVet) in Australia.

Key relevant GPA responses previously submitted include:

- *Response to Department of Agriculture Proposed Agricultural & Veterinary Chemicals Legislation Amendments Consultation Paper (7 March 2014)*
- *Response to Australian Government Senate Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (17 April 2014)*
- *Response to Australian Government Agricultural Competitiveness Issues Paper (17 April 2014).*
- *Grain Producers Australia response to Department of Agriculture First Principles of Cost recovery at the APVMA final report (24 October 2014).*
- *GPA response to the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 (19 July 2017).*

As detailed in previous submissions by GPA, it is recognised that Australia is no longer on the global priority list for pesticide and veterinary medicine investment in commercialisation as it was 20 years ago. It is essential that unnecessary reviews and red tape does not further erode Australian AgVet investment and resulting productivity through reduced technology access. It is important that APVMA reviews are based on science-based evidence where adverse events or new international scientific evidence calls for reconsideration of existing chemical actives.

The Australian grains industry is not resourced to meet the potential significant cost of an unnecessary regulatory process where time bound compulsory re-registration is likely to result in commercial market failure for regulatory support of generic off patent chemical actives. Australia is also missing out from productivity improvement through commercial investment in a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies. It is essential that Australian grain growers have access to the same pesticide technologies to remain internationally competitive with other overseas producers,

While GPA is responding positively to initiatives and some of the key changes in the Agricultural and Veterinary Chemicals Legislation Amendment exposure draft (Streamlining Regulation) Bill 2018 the key deficiency of the proposed changes is that it does not address the declining commercial pesticide investment into Australia. Proposed incentive programs in the legislation are likely to result in unintended consequences, further slowing industry access to technology.

Consultant Dr Rohan Rainbow, is a consultant to GPA on all AgVet chemical related issues. He has previously facilitated discussions with most of the agricultural industry RDCs, Department of Agriculture and Water Resources, APVMA and key registrant groups CropLife Australia and the Animal Medicines Australia to identify the major factors resulting in declining investment in Australia which include;

- Australia is a small market in a global context < 1.5%
- Since the last round of AgVet reforms in 2014 and 2017, Australia is continuing to experience difficulties with complex AgVet regulations, timeliness and costs relative to commercial return on investment
- Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China.

GPA response to issues as outlined in the exposure draft and accompanying documentation.

In providing a response on the key issues outlined within the exposure draft the GPA would like to make the observation that there is some conflict between the exposure draft and the explanatory memorandum with relation to the use of the words “May” and “Must”. There is a need to ensure clarity where it is proposed that the word “May” in the current legislation is to be replaced with the word “Must” as this can be a significant and in some cases detrimental change. If there were further proposed changes to the either the legislation and regulations then we would expect clear and transparent consultation with industry.

Provisional registration of chemical products

GPA **partly supports the proposed approach on reforms for provisional registration of chemical products, however this should be extended to chemical residues.** GPA in previous submissions has proposed a provisional registration program of chemical products. GPA has proposed the establishment of a provisional and/or conditional registration system with fee payment deferral options based on agro-ecological co-equivalence and same use in crops/animals overseas;

- Delivering technology to agricultural industries faster
- Increasing incentive to commercialise technology in Australia
- Provisional review self-funded through sale of product.

The proposed legislation change does not deliver on this proposal. The legislation does not remove the need for local Australian efficacy data generation. The outlying costs will still remain and where market failure exists the cost will often be borne by industry Research and Development Corporations (RDCs).

While there is a proposal for provisional approval of efficacy data, it does not remove the requirement for Australian residue trial data, which is the more significant cost barrier to registration in Australia. GPA considers that provisional registration of residue data should also be included if agro-ecological co-equivalence and same use pattern can be demonstrated in overseas registrations.

GPA following consultation with the Grains Research and Development Corporation (GRDC) is concerned that the proposed legislation may increase investment market failure with registrants, pushing a investment needs towards RDCs. There is also concern that there will be a cascading effect for increased RDC investment to deliver data on efficacy criteria.

Accreditation of assessors

GPA **partly supports the proposed approach to reforms on accreditation of assessors, however limitations of liability need to be recognised.** GPA recognises that there has been an APVMA pilot study using external assessors. GPA considers that there is significant opportunity for implementation of third party APVMA approved certifiers rather than current APVMA monopoly;

- This approach has been implemented successfully in New Zealand
- The approach could be successfully implemented specifically for an industry led minor use program
- Would go some way in addressing the current critical shortage of regulatory expertise at the APVMA

There is a need for specific legislative instruments to protect the liability to these assessors with final decisions and liability risk being held by the APVMA. Limitations of liability from negligence will need to be in place, otherwise the cost of insurance premiums for external assessors are likely to be make the program unviable.

Approval and registration for prescribed active constituents, products and labels

GPA **partly supports the proposed approach to reforms for prescribed approvals and registrations**. The reforms will reduce industry cost and speed up changes to approvals for those active constituents, chemical products and labels where minimal or no assessment of technical information was required. From the Australian scientific community, GPA is aware that in some cases, formulation changes with some chemical herbicide products has resulted in major changes to efficacy, particularly where lower manufacturing cost formulations have been used. There is potentially a need for new efficacy data where formulations and formulation specifications appear to differ significantly from the original registration.

Data protection incentives (limits on use of information)

As detailed above, GPA has proposed new incentives to address the significant issue of investment market failure of AgVet investment in Australia. The impact of this declining investment is highlighted in table 1 comparing differences in pesticide technology access for Australian grain growers with the USA. This data clearly identifies a significant problem from a lack of investment as growers are impacted by the 'double whammy' of lack of new, more advanced pesticide options delivering productivity outcomes, plus accelerated selection pressure for pesticide resistance due to a narrow pool of products. This situation has not improved since 2014 and commercial investment in new pesticide technologies appears to have become worse in recent years.

Table 1. Comparison of first registered labels between Australian and USA.

Grain crops highlighted in red

Comp.	Compounds	Type	Trade name	Australia – Initial registered Uses	Aus Reg Date	USA – Initial Registered Uses	US Reg date
Bayer	Penflufen	Fung	Evergol Prime ST	Wheat and barley	2012	Alfalfa, Cereal Grains, Corn , Cotton, Legume Vegetables, Oilseed Crops, Rice, Soybean , Tuberous & Corm Vegetables	2012
Syngenta	Sedaxane	Fung	Vibrance ST	Barley, oats, triticale & wheat	2012	Canola, Cereal Grains, Corn, Soybean	2012
Dupont	Penthiopyrad	Fung	Fontelis	Pome fruit, stone fruit, tree nuts, brassica vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, root & tuber vegetables and bulb vegetables.	2012	Alfalfa, Bulb Vegetables, Brassica Leafy Vegetables, Canola, Cereal Grains, Corn , Cotton, Cucurbits, Fruiting Vegetables, Leafy Vegetables, Legume Vegetables, Low-growing Berry, Peanut, Pome Fruit, Root & Tuber Vegetables, Soybean , Stone Fruit, Sunflower , Tree Nuts, Turf, Ornamentals	2012
BASF	fluxapyroxad	Fung	Imbrex	Barley	2012	Barley; Corn (field, pop, sweet); Bean & Pea, dried-shelled; Bean & Pea, succulent-shelled; Edible-podded Legume Vegetables; Fruiting Vegetables; Oat; Oilseed Crops; Peanut; Pome Fruit; Rye; Soybean; Stone Fruit; Sugar Beet; Tuberous & Corm Vegetables; Wheat	2012
Syngenta	prosulfuron	Herb	Casper	Turf	2012	Field corn , pop corn, sorghum	1995
BASF	Saflufenacil	Herb	Sharpen	Pre-plant BL weed control	2012	Cereal Grains; Citrus; Cotton; Foliage of Legume Vegetables; Forage, Fodder, & Straw of Cereal Grains; Grape; Legume Vegetables; Pome Fruit; Stone Fruit; Sunflower; Tree Nuts	2009
Bayer	Pyroxasulfone	Herb	Sakura	Barley & wheat	2011	Corn, soya bean	2012
Bayer	Foramsulfuron	Herb	Tribute	Turf	2011	Corn , turf	2003

Source: compiled by Kevin Bodnaruk AKC Consulting Pty Ltd for Horticulture Innovation Australia Limited

GPA supports the government in engaging in a discussion on potential incentives to support increased AgVet investment into Australia to provide the tools and production capacity for industry to remain internationally competitive.

GPA does not support the proposed legislative initiative reforms as proposed. Reforms to the legislation do not link the proposed incentives to industry need or priorities. The proposal to limit extension of the protection period only if the application to vary an existing registration is made at

least three years before the limitation or protection period for the information associated with the existing registration expires, will result in companies delaying decisions for support of minor crops and where market failure exists.

Potential outcomes will be that chemical companies will potentially slow down investment in minor and new crops and data protection, the resulting effect will be a slow down in the rate of industry access to new products and a skew of investment into crops that may not meet the gaps identified by industry. The incentives also don't reflect the amount of effort or cost to deliver technology for some industries. There is a need for incentive benefits that stretch data protection out to 3 to 5 years to be a higher bar of effort than a single year of extension. While the proposed legislations recognises this with a proposed twelve months additional limitation or protection period for the use of a chemical product on each entire crop or animal commodity group, this should only be allowed where the group priority is support by the relevant industry through an identified priorities list.

Incentives must be linked in the legislation to a list of industry priorities. Reference to a list of industry priorities by the government should include the list delivered through the successful AgVet Collaborative Forum, currently supported by all plant industry RDCs. A project and report funded by the Department of Water Resources through RIRDC, Delivery of Access to AgVet Chemicals Collaborative System – AgVet Collaborative Forum² established this process and manages a current list of industry priorities and needs³. The process used to develop this list is largely based on the Canadian government minor use priority setting process, incorporating some of the process from the USA IR-4 minor use program. Like these North American programs, the Australian government should consider additional financial incentives to underwrite an Australian minor use program such as fee waivers and discounts, particularly where generic compounds are involved.

The intention from this legislative change is to reduce market failure, but in effect the proposal is likely to make market failure worse and more importantly, it will be hard to wind back the commercial impacts once implemented. GPA has previously suggested a number of incentive reforms likely to address market failure without any resulting additional cost to the government or regulators. These include;

Establish a points credit system for registrants who put minor use needs onto label being rewarded with an option for acceleration of an alternate registration evaluation priority, to incentivise commercial investment in industry priorities where market failure exists. These credits could then be used to accelerate other applications being assessed perhaps even at a later time eg. 6-12 months later allowing the build up of credits;

- Would be a self-funding program by registrants
- Delivering minor use and new technology onto label to industry faster
- Encourages parity with international labels for agriculture.

Adopt in new AgVet legislation and regulations improved data protection for emergency and minor use permits to improve the value proposition and incentive for commercial investment, encouraging contribution of exiting Australian and International data to these programs. In addition provide data protection incentives on existing registered labels encouraging investment in minor use through adopting a USA based system of 1 extra year for 3 minor use label extensions would;

- Be self funding program by registrants
- Potentially provide incentives for additional label registration of minor uses
- Improve product stewardship through company label communication

² <https://www.agrifutures.com.au/wp-content/uploads/publications/17-019.pdf>

³ <https://www.agrifutures.com.au/national-rural-issues/agvet-chemicals/>

Increased Federal Government support and legislative incentive to build on the AgVet Collaborative Forum - now established cross agricultural industry minor use program supported by all Australian plant industry RDCs resulting in;

- Improved priority setting and cost sharing
- Achieving Government, RDC and Commercial co-investment in data generation
- Achieving cost savings through cross industry efficiencies and international collaboration and co-investment with IR-4 USA and Canada.

There are significant barriers to companies contributing protected data to minor and emergency use permits, particularly if this is new international data to Australia which would not have already been protected through a label application process. The potential opportunity for increased data protection would provide incentive for greater investment by commercial manufacturers in minor use programs in Australia and this would also potentially support a longer-term objective of an increased number of permits being transferred to label registrations.

To address investment market failure in the longer term, there is need for transformational change to AgVet regulation in Australia. This should include consideration to full international co-regulation with a major technology development country. A transition to this could be supported through an interim provisional and/or conditional registration process. This will increase multinational confidence for investment into Australia and also increase Australia's ranking on investment priority compared with competing investment opportunity in Asia and South America. This initiative would deliver;

- Consumer and government confidence in broader international standards
- Cost savings to Australia
- Fastest possible technology access for agricultural industries
- Ensuring Australia is on the first priority commercialisation list.

These options would capture not only minor uses, but also major uses where there is demonstrated market failure for investment and a need for additional investment intervention. There is a need to expand the minor use definition to not only those industry needs that are of low economic value to a registrant but also for situations where there is insufficient approved options for pest management or where investment market failure occurs impacting on industry productivity.

If Australia were to effectively collaborate with IR-4 in the USA, then there will need to be some government appropriation for an Australian equivalent. An investment model, which is at odds with the USA system, would be a significant disincentive for international collaboration with Australia. To address this, there is a need to consider amendment to regulations so that no fee is payable (or is reduced to a certain percentage) if the use qualifies as a priority by *'written submission in a prioritised list by the government nominated representative peak agricultural industry organisation or relevant research and development corporation defined under the PIERD Act'*

There are significant advantages of having industry-linked incentives in place as soon as possible to encourage industries to participate in priority setting process and additional industry and commercial investment. This includes the USA IR-4 approach of priority review by the USEPA for support of key industry priorities. Having these linked in the legislation, particularly in terms of fees and assessment timeframes would be an excellent initiative to deliver rapid benefits to industry and the community.

Information to be taken into account in determining applications

GPA supports the proposed approach to reforms for prescribed approvals and registrations. Reforms that speed up the evaluation process and avoid unnecessary delays for new chemical approval should be implemented in legislation.

Computerised decision-making

GPA supports the proposed approach to reforms to modernise the Agvet Code by providing for the APVMA to use computerised decision-making. There is an urgent need for the chemical industry to transform from current 19th century paper based systems into a 21st century smart digital agriculture system. There is also the additional need for legislative reform that allows for the outcome of the decision making process to result in an electronic label as an alternative to the current paper based output. These changes should also be reflected in state control of use legislation to support the implementation of electronic labels. This will allow for the future integration of label information into computerised spray control systems that will facilitate the integration of autonomous machine control.

Voluntary recalls

GPA supports 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.

Notification of new information

GPA supports the reforms ensuring that obligations to allow 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.

Standards for registered chemical products

GPA supports the reform to enable label holders to make reasonable variations, reducing the regulatory burden on industry and the APVMA by allowing defined variations to the constituents in chemical products.

Suspensions or cancellation of approvals and registrations for providing false or misleading information

GPA supports the reform to address the anomaly in the AgVet Code whereby the APVMA is unable to suspend or cancel an approval or registration where false or misleading information is given.

Addressing an inconsistency in label particulars (supply with unapproved label)

GPA supports the reforms addressing an inconsistency in label particulars. GPA agrees with the Department that legislative amendment is required to clarify the nominated agent and the holder of approval, as opposed to the marketer of the product.

Variation of approval or registration during suspension

GPA is concerned with the proposed changes to the reform on variation of approval or registration during suspension. GPA understands that in a number of cases there is a need for a more pragmatic mechanism to vary a suspended chemical product registration. There needs to be flexibility in the options to deal with the problem that led to the initial suspension of registration to then allow the chemical product to be put back on the market.

There is however significant concern that this reform may result in a weakening of registrants taking timely responsibility for the registration of their products. There is a risk that some registrants may continue to manage these situations after the effect. There is a need for a restriction or penalty to use this mechanism if there is continued suspension situations arising.

Prescribing matters for the statutory criteria

GPA does not support this proposed change in legislation to matters that can be prescribed for the statutory criteria (safety, efficacy, trade and labelling criteria). GPA understands that the

APVMA has advised that they are already maximising the use of international standards, assessments and data in its assessments. There is clearly no need to introduce a legislative requirement for compulsory consideration of international data. Registrants have the right to include international data to support label applications and the legislation should reflect the right for this data to be considered in a label application. The current exposure draft of the Agvet Bill and the explanatory notes supplied appears contradictory;

'5E Overseas trials and experiments

Without limiting subparagraph 5A(2)(a)(vii) or (3)(a)(vii) or paragraph 5B(2)(d), 5C(2)(c) or 5D(2)(d) and despite section 160, the matters prescribed by regulations made for the purposes of that subparagraph or paragraph may relate to matters covered by paragraph 160(2)(a), (b) or (c)'.

The Department consultation document details that the APVMA **must** rather than **may have regard** as per the Bill exposure draft;

'Proposed approach

The government proposes to correct the anomalies in the statutory criteria by amending the Agvet Code to provide that:

- regulations, if made in the future, may prescribe matters the APVMA **must have regard** to for the purposes of being satisfied that a label meets the labelling criteria, similar to the current regulation making powers in sections 5A to 5C of the Agvet Code*
- regulations, if made in the future, could prescribe that the APVMA **must have regard** to the matters in section 160 of the Agvet Code (overseas trials and experiments, which could include international standards, assessments and data)'.*

This change will unnecessarily increase the operational demands of the APVMA, requiring unsolicited review assessment under their normal assessment process. The requirement for the APVMA to consider international data included in a label registration application should be based on the need to review data as submitted by the registrant. There are also sovereignty risks to creating legislative review triggers in Australia based on overseas information from this amended legislation.

Removing the need for an annual operational plan

GPA does not support the removal of the requirement of an annual operational plan in addition to the corporate plan required annually under the *Public Governance, Performance and Accountability Act 2013*. GPA believes that the publication of the annual operational plan provides transparency of its operational plans, which will be additionally supported by the proposed re-establishment of the APVMA board.

Aligning the 2014 legislation review with the current review of AgVet chemical legislation

GPA does not support the planned alignment of review measures in AgVet chemical legislation. There should be a separate review of the impact of changes from the 2018 Bill. The 10 year review of the AgVet chemical regulatory framework under section 72 of the Administration Act should be conducted separately and consider the broader strategic issues of future legislative reforms including digital data, labels and systems, autonomy in application and use in legislative label consideration and reforms taking allowing consideration of new science of chemical, biological and biochemical technology.

Other comments for future AgVet legislative reform

As detailed in previous submissions to the Department by GPA, agriculture is facing significant challenges in being able to deal with the future resistance threats and emerging plant and animal

health issues. Many agricultural industries, particularly grains will experience significant productivity losses in 8-10 years through the combined impacts of pesticide resistance evolution and the limited access to new technologies. With a lead-time of 7 to 10 years to deliver a commercial technology that has already demonstrated proof of concept, Australia cannot afford an increased burden of unnecessary costs.

Options that could be implemented through further legislative AgVet reform delivering productivity outcomes for industry including an improved approach to minor use and specialty needs of pesticide and veterinary medicines have been proposed following consultation with many RDC's and peak industry bodies. An option includes;

Establishment of formal collaboration with USA and Canada through IR-4 minor use programs, establish an Australian minor use program cost recovery model, which mirrors these overseas programs with supporting legislation to ensure efficiency of this program;

- Delivering cost savings, which would need to be based on co-equivalence of cost recovery models for evaluation
- Delivering technology to agricultural industries faster
- Increasing international confidence of Australia as a cost effective investment option.

GPA commitment to further reform discussion

There is an urgent need for the chemical industry to embrace digital agriculture and automation technologies and the legislation must embrace these 21st century technologies and encourage the consideration of these systems by the APVMA. There is also an urgent need for reforms to enable electronic labels and for these changes to be reflected in state control of use legislation.

GPA is committed to further discussion with the Australian and state governments on the need to deliver transformational change delivering improved pesticide technology access and stewardship in the Australian agricultural industry. There is commitment from GPA to work cross industry and deliver productivity outcomes to agricultural industries and the Australian economy and community.

If you would like to discuss any of these comments and suggestions further in detail, please contact me on email andrew.weidemann@grainproducers.com.au or 0428 504 544.

Yours sincerely



Andrew Weidemann
Chairman
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