SUBMISSION

GPA response to the consultation on operation of the amendments in the agricultural and veterinary chemicals legislation amendment act 2013

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Thank you for the opportunity for Grain Producers Australia (GPA) to provide a response to the **GPA consultation on operation of the amendments in the agricultural and veterinary chemicals legislation amendment act 2013**[1]**.** The GPA submission is made on behalf of all our members including the State Farming Organisations. In some cases State Farming Organisations will make a separate submission to more clearly articulate state based concerns.

Executive summary

GPA provides the following overview of comments on the operation of the amendments in the agricultural and veterinary chemicals legislation amendment act 2013. Further clarification of the rationale behind these comments are contained within the body of the submission.

- The retraction of (Schedule 2 – 47A - *Re-approval and Re-registration*) from the 2013 Act - was an important outcome for technology access for Australian agriculture
- A number of important issues were not addressed or justified in the legislation amendment act 2013 including:
    - Use of the Risk Analysis Framework to determine how the level of risk will be aligned to the required level of assessment
    - Justification for the introduction of a re-approval and re-registration scheme
    - Development of a minor use program.
- GPA considers as an outcome of the 2013 Act that the current timeframe for chemical reviews do not meet industry and community expectations.
- Significant delays for approval of new active products is a significant cost to industry with delays in access leading to combined productivity losses and accelerated impact of pesticide resistance.
- There is a need for pragmatic discussion on what legislative reform is required to speed up the APVMA assessment timeframe for new actives.
- The is a significant issue of increasing market failure of AgVet investment in Australia and this situation has not improved since 2014 since implementation of the 2013 Act. Commercial investment in new pesticide technologies compared to the USA and Canada appears to have become worse in recent years.
- There should be significant consideration of models based on international datasets if the case can be made for agro-ecological co-equivalence and similar good agricultural practice.
- 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. Legislative reform is required that allows for the outcome of an electronic label.
- GPA would support the Australian government to engage 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 removal of *Part 3 of the AgVet Code to allow stakeholders to rely on commercial arbitration legislation* as this would potentially lead to registrant uncertainty of maintaining CCL and data protection and a consequential loss of investment confidence in commercialising new AgVet technology in Australia.

[1] https://acilallen.com.au/AgVetreview

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:

- *GPA response to Department of Agriculture Proposed Agricultural & Veterinary Chemicals Legislation Amendments Consultation Paper (7 March 2014)*
- *GPA 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)*
- *GPA 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)*

- *GPA response to the consultation on Agricultural and Veterinary Chemicals Legislation Amendment exposure draft (Streamlining Regulation) Bill 2018 (22 August 2018)*
- *GPA response to the Senate Committee on Rural and Regional Affairs and Transport on Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (19 December 2018).*

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 the Australian Government initiative of ongoing legislative reform, key changes in the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013 and subsequent reform bills do not address the declining commercial pesticide investment into Australia. While there is clearly many limitations of how the regulator can operate under the 2013 and subsequent AgVet Acts, GPA would like to commend the APVMA and its staff in supporting the Australian grains industry with effective and timely communication on key chemical access issues including permits and the ongoing product registration needs of the industry.

GPA consultant on all AgVet chemical related issues, Dr Rohan Rainbow 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.

As detailed in previous 2014[2], 2017[3] and 2018[4] 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

[2] GPA response to Australian Government Senate Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014
[3] GPA response to the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017
[4] GPA response to the Senate Committee on Rural and Regional Affairs and Transport on Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018

- 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.

GPA has reviewed previous February 2012 Grains Research and Development Corporation submissions to the 2013 AgVet Act and recognises that the reforms could have potentially improved efficiencies and reduced time frames for application assessments and chemical reviews. A wider range of enforcement tools should also have enabled the APVMA to better ensure compliance with regulations. However GPA notes that data protection reforms to application processes could have removed some disincentives to seeking permits, re-approvals and re-registrations. The cost of generating data is likely to remain a disincentive for minor uses and generic products. More recent regulatory reforms detailed in the Agricultural and Veterinary Chemicals Legislation Amendments (Operational Efficiency Bill 2017 and 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 new 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.

Feedback on AgVet (Removing Re-approval and Re-registration) Act 2014

GPA notes that the provisions establishing the re-approval and re-registration scheme only operated for a short time until they were repealed by the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (Removing Re-approval and Re-registration Act), The removal of Schedule 2 – 47A from the 2013 Act relating to varying duration—decisions of foreign regulators was supported by GPA. GPA had significant concern in 2013 that this section would have potentially forced the APVMA to consider a large number of such compounds upon the implementation of the EU hazard-based regulatory scheme, i.e., where use of a compound with dual applications may be prohibited in the EU on the basis of hazard-based policy rather than risk as considered in Australia.

The repealing in 2014 of certain components of the 2013 Act removed legislation for an additional trigger for the APVMA to reconsider a chemical product when 2 or more of 7 nominated overseas regulatory authorities have prohibited the use of the chemical on safety grounds (Schedule 2 – 47A). There was additional concern for plant industries because these agencies cover both the crop and

veterinary sectors and that problems may emerge for compounds with uses in both areas, e.g., deltamethrin, cyromazine or abamectin.

The retraction of (Schedule 2 – 47A) from the 2013 Act was an important outcome for technology access for Australian agriculture and productivity impacts, as a large number of actives have been voluntarily withdrawn in the EU following the introduction of EU directive 91/414/EEC primarily due to manufacturer commercial considerations and market failure. The value proposition and return on investment for companies to meet the costs of regulatory defence has resulted in some two thirds of pesticide actives in the EU being lost to agricultural industry not necessarily due to science-based human health or environmental concerns, but due to investment market failure and companies favouring products with a patent or higher investment return. This includes actives in the UK that were included in the proposed regulations. The highly subsidised agricultural industry in the EU has been able to absorb some of the impact of these decisions.

GPA supports the government's decision in repealing Schedule 2 – 47A from the 2013 Act, that APVMA reconsiderations are based on science-based evidence or adverse events for reconsideration of existing chemical actives, not on the basis of investment market failure. The Australian grains industry and GRDC is not resourced to meet the potential significant cost of this market failure for regulatory support of generic off-patent chemical actives.

Feedback on AgVet Chemical legislation amendment act 2013

GPA would like to note that a number of important issues were not addressed or justified in the legislation amendment act 2013 that were identified in a 2012 Grains Research and Development Corporation submission[5] to the Department of Agriculture, Fisheries and Forestry:

- Use of the Risk Analysis Framework to determine how the level of risk will be aligned to the required level of assessment
- Justification for the introduction of a re-approval and re-registration scheme
- Development of a minor use program.

GPA provides a response under the suggested review themes;

Theme 1: Application assessment efficiency and effectiveness

- *The effectiveness of the 'elapsed time' model versus the 'stop the clock' model, and whether the elapsed time model can be made more flexible through broadening the scope of 'time-shift' applications.*

Timely chemical review by the APVMA is critical to both support producer access to new chemical technologies and also to meet community expectations and support consumer and market confidence when new science knowledge arises. GPA conducted a telephone interview survey of six multinational chemical companies in May 2017 focusing on direct impacts to the grains industry from the Federal Government APVMA relocation policy and resulting outcomes to the grains industry from impacts of APVMA staffing resources and delivery timeframes.

The impact was estimated from combined impacts of delays to three products, two new fungicides and one new herbicide (noting all have now been approved and registered by the APVMA in early 2018). The estimates were based of the survey of chemical companies conducted by GPA in May

[5] GRDC submission to Department of Agriculture, Fisheries and Forestry detailing comments in relation to GRDC research delivery under the draft Agricultural and Veterinary Chemicals Legislation Amendment (Agvet) Bill 2012 – 19 October 2012.

2017 and potential impacts from use of these chemicals and risks (seasonal dependant) based on the resistance management benefits, severity of the issues that these products resolved and the resulting effective control of particular diseases and weeds. GPA understanding from the survey is that these product registrations were delayed by one season for access by industry. At the time of the survey, the companies were anticipating this could be two seasons. The reference to impacts of further delays is also in reference to key new herbicide products for use in cereal production that due to the severity of herbicide resistance management, will have significant economic impact if there are registration delays; If the situation lasts for another 2 years with a delay of 12 months on major projects, GPA estimates the minimum impact through lost productivity and accelerated pesticide resistance evolution to the grains industry would be well over $1 billion.

GPA estimates of values for the cost of herbicide approval delays are based on delays to a new grass/broadleaf herbicide for use in canola and future impact on a new MOA cereal herbicide scheduled for release on the 2020 season. Estimated losses based on a GRDC review of weed economic impacts[6] include:

- Herbicide resistance was estimated to cost $187 million in additional herbicide treatment costs, in addition to the costs of using extra integrated weed management practices
- Weeds in fallows are estimated to be costing more than $430 million through reduced crop yields
- Overall, revenue loss due to weed populations reducing crop yields was $33/ha, which is similar to the cost of some herbicide applications
- Yield losses due to weed competition from residual in-crop weeds were valued at $278 million
- The overall cost of weeds to Australian grain growers is estimated to be $3,300 million.

2017 GPA estimates of disease impacts were based on delays to a new MOA canola fungicide for blackleg control, which is desperately needed, and a new cereal fungicide for resistant mildew control, also desperately needed. Estimated losses based on a GRDC review of disease economic impacts include:

- Potential yield loss of 19.3% and present yield loss of 7% from powdery mildew in WA only based on a barley crop valued at $650 million (WA only) is equivalent to a $45 million loss and potential of $125 million based on 2012 figures[7], however this situation has significantly worsened since six years ago, noting that resistance in powdery mildew in wheat in eastern Australia is also increasing. 2012 figures indicate potently losses of 58.9% and current losses in wheat of 16.4%[8].
- Current losses from blackleg in canola is $76.6 million and potential losses of $331.3 million based on a crop value of $500 million[9]. Without an effective alternative new mode of action fungicide for blackleg control, based on current resistance development to exiting registered fungicides, the industry is looking at this upper estimate of losses.

The combined GPA estimate of economic impact of pesticide evaluation delays of $200 million was derived from these combined values of impact. These estimates could potentially increase to $500 million if resistance issues substantially increased. GPA considers that the estimates previously detailed in the 2017 submission were conservative and could easily be higher than these estimates.

GPA considers that the current timeframe for chemical reviews do not meet industry and community expectations. The proportion of pesticides approved by the APVMA before deadlines bottomed at 24

[6] https://grdc.com.au/resources-and-publications/all-publications/publications/2016/03/impactofweeds
[7] https://grdc.com.au/__data/assets/pdf_file/0025/204748/disease-loss-barley.pdf.pdf
[8] https://grdc.com.au/__data/assets/pdf_file/0026/203957/disease-loss-wheat.pdf.pdf
[9] https://grdc.com.au/__data/assets/pdf_file/0021/82641/grdcreportdiseasecostoilseedspdf.pdf.pdf

per cent between April and June 2017[10], which has subsequently improved reaching 86% for the September 2018 Quarter[11]. What is of significant concern are the delays to approval of new active products with only 44% of approvals being achieved against the legislated timeframes. There is a need for pragmatic discussion on what legislative reform is required to speed up the APVMA assessment timeframe for new actives. This will continue to be a significant cost to industry with delays in access leading to combined productivity losses and accelerated impact of pesticide resistance.

- *Whether the amendments have assisted stakeholders with the application process.*

The additional disruption resulting from the APVMA relocation program Armidale has also clearly impacted on ability to deliver timely assessment outcomes, not only for registration of new chemical products but also ongoing review of prioritised chemicals. While assessment timeframes by the APVMA appear to be improving over recent months, registration timeframes specifically for new mode of action chemicals continue to be significantly delayed. Companies indicated they would like to be optimistic and recognise that there is still time for the APVMA to recover some of the impacts from the current situation. Consensus from company interviews is that that the delay situation impacting on new active approvals is likely to become much worse over the next 2 years - resulting longer-term impact is likely to result in reduced overall development investment in agricultural chemicals. Companies expect it is likely to take up to 5 years for the APVMA to recover from the current lack of technical staff resources, with all companies noting there is a global shortage of regulatory experts. There is a need for legislative reforms to more effectively enable access to these key skills and streamline the approval process.

GPA has also made previous submissions to the APVMA providing feedback on model evaluation frameworks, which will assist with timely and efficient delivery of regulatory assessments[12]. There should be significant consideration of models based on international datasets if the case can be made for agro-ecological co-equivalence and similar good agricultural practice (GAP). For example the APVMA currently proposes that a model would be considered inadequate if all parameter data is obtained from overseas studies, even though suitable Australian data is not available. This decision especially in consideration of mechanistic models should only be made if there is clear case for requiring unique Australian data. It would not be appropriate to require the significant cost to industry and registrants to re-generate uniquely Australian data if the justification for this is not warranted. GPA suggest that the reference to international data use in the evaluation framework is re-considered and should be discussed further with industry and registrants before finalisation.

The Australian grains industry through levies paid to the GRDC has made significant investment in the development of a number of mechanistic models that have been designed to be used in future regulatory decisions by the APVMA. These models have been or are in development to be used as tools by producers to achieve effective and environmentally outcomes from pesticide use. It is important that the potential use of these models, both Australian and international is supported through legislation. It is essential that the APVMA utilises these models in their most effective way for prediction of outcomes, not just using them as tools to simplify regulatory decisions on labels, but also for use of these models as a reference tool and use guide on labels to improve industry best practice. Examples of these models include:

- GRDC Project UQ00047 An interim model for buffer zone reduction in pesticide application from ground sprayers Australian Ground Spray Calculator (AGSC)

[10] https://www.smh.com.au/politics/federal/conflict-of-interest-warning-as-mps-weigh-bid-to-ease-apvma-strain-20190201-p50v31.html
[11] https://apvma.gov.au/node/39211
[12] GPA response to the APVMA Model Evaluation Framework – 3 October 2017.

- GRDC Project UQ00072 - Spray application management (DRT modelling, managing surface-temperature inversions and spray quality effects on herbicide efficacy)
- GRDC Project DAW00231 The study 'Management of spray drift through inversion risk awareness

GPA is also aware of private investment in risk assessment models that would significantly speed up the efficiency APVMA regulatory decisions. An example of this includes; Pesticide Environmental Risk Assessment Model for Australia (PERAMA) by Australian Environment Agency Pty Ltd. This model is already used by commercial registrants to efficiently consider potential environmental terrestrial and aquatic impacts. There is a need to ensure that the APVMA adopts and uses these types of tools to speed up regulatory evaluation as an alternative rather than an addition to existing processes.

For models such as spray drift reduction technology (DRT) models, these models should ideally be held by the APVMA and made available to registrants and industry producers as a reference for best practice use. GPA is concerned that models may only be used as look-up tools, however into the future where automation and digital agriculture technologies will be significant enablers, models can be delivered as active on-line tools that can interact with future label guidelines. If there are legislative blockages to this pathway, the GPA would like to discuss the detail of these bottlenecks with the APVMA.

GPA is concerned with the delays already experienced with assessment of the GRDC funded spray drift models which have been submitted to the APVMA, and also tabled and discussed at length through the National Working Party for Pesticide Applications. Appropriate use of this model by the APVMA and industry outcomes through application of DRTs by producers should already be in place. GPA is also concerned that outcomes of the spray drift review and consideration of application of this new model in regulatory decisions are not yet in place before the reviews of phenoxy herbicides including 2,4-D have are finalised. It is essential that chemical review regulatory decisions are deferred until full consideration for decision on models submitted are finalised, including the new spray drift and DRT models.

The APVMA should be able to maintain confidential commercial information (CCI) and data protection both for the data being assessed and the model itself. It is essential that CCI and data protection is maintained to ensure that there is a business model for continuous improvement and updates of many of these models. It is important that the APVMA considers proprietary models in the assessment framework. Where proprietary models would deliver significant improvement to assessment timeframes, the APVMA should seek a license to access these models, potentially on a fee for use basis.

GPA supports the establishment of an approved list of models. Certainty of regulation will lead to improved confidence in investment. Models considered in this list should include published public, restricted access models by legislation (as in the case of air inversion risk models) and commercial or proprietary models. The list of models should not be restricted to only full public access models. In the case of the use of commercially developed or proprietary models such as PERAMA, the APVMA should be prepared to consider the use of these models for internal assessment on a commercial fee for use basis for regulatory evaluation, both for use by registrants in their applications and also by the APVMA in making efficient regulatory assessments, particularly if the models are validated and approved through the proposed evaluation framework.

Label reference to producer use of models, which improve stewardship and use such as DRT models, would simplify future changes to regulatory outcomes and the need for continuous label change or improvement. For example if a new DRT technology is established, validated and a revised model is approved by the APVMA, then both registrants and producers would benefit from faster access to the

validated legal use of a new DRT, while at the same time delivering faster access to environmental benefits from the use of these technologies. It is essential that the APVMA consider how models can be effectively used under current AgVet legislation to deliver the key objectives of the organisation of production, trade, operator and environmental safety. If there are legislative blockages to this pathway, the GPA would like to discuss the detail of these bottlenecks with the APVMA.

- *Whether there should be more flexibility in the time period used to rectify defects in applications.*

GPA recognises that submission of incomplete applications with significant defects creates significant challenges for the APVMA in meeting assessment timeframes. There is ongoing concern that some registrants use the resources of the APVMA in managing up through the submission process to address defects in applications. Registrants should be utilising the preliminary assessment process to avoid this situation being a regular issue. GPA agrees there can be a case in some situations with technically difficult applications for more flexibility in the time period to rectify defects in applications, particularly where the generation and assembly of this data requires significant industry coordination. However there is potentially a case to penalise registrants who regularly abuse the application process with regular submission of incomplete applications with defects to avoid APVMA resources being unnecessarily tied up addressing these issues.

- *Whether the preliminary assessment step should be retained.*

The preliminary assessment step should be retained as this has been an instrumental tool for industry managing key challenges of emerging pest management issues, including industry permits and labels for mouse management with zinc phosphide and late season weed management with glyphosate in barley. GPA considers that the preliminary assessment step is an efficient mechanism to ensure completeness of applications leading to timely assessment.

- *The value and practical effects of the APVMA's use of international assessments and data for assessing applications*

GPA understands that the APVMA has advised that they are already maximising the use of international standards, assessments and data in its assessments under the 2013 Act. There is clearly no need to introduce a legislative requirement in the 2018 Act reforms - *Prescribing matters for the statutory criteria (Part 12 of Schedule 1 - Items 85 and 86)* 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 2018 Bill details that the APVMA **must** rather than **may have regard**. *The government in the 2018 Act 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.

- *Any other issues (caused by the amendments) relating to the efficiency and effectiveness of assessments.*

There has been an ongoing need for legislation to support access to external assessors to enable the APVMA to meet its legislated assessment timeframes. More recently this initiative has been extended through further legislative reforms where GPA partly supports the proposed 2018 AgVet Bill reforms on accreditation of assessors (Part 5 of Schedule 1), 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.

A key deficiency in the 2013 Act was a lack of reform and improvement to the minor and emergency use program, which currently constitutes around 30% of all APVMA product approvals for use[13]. An effective minor and emergency use program is extremely important for the grains and other agricultural industries in addressing the needs of emerging industries and providing effective response to rapidly emerging pest and disease threats. GPA considers the minor and emergency use assessment and approval mechanisms a critical program to ensure timely delivery of industry pest control measures.

There has been considerable discussion between the grains, horticulture and emerging crop industries in regard to potential improvements in collaboration and coordination programs to manage minor use registrations. 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 Forum established this process and manages a current list of industry priorities and needs . 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.

While there have been recent proposals for legislative change in the 2018 Act, the proposed approach which was removed from the Bill would likely have made market failure worse and more importantly, would have been 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:

I. *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

[13] https://apvma.gov.au/node/39216

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.

II. *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

III. *Increase Federal Government support and legislative incentives 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.

Theme 2: Reconsiderations (chemical review)

- *Whether the amendments, including the published work-plans and timeframes, have improved the transparency and predictability of reconsiderations.*

GPA is committed to further discussion with the Australian government and the APVMA to maintain environmental credentials for the grains industry while delivering safe and effective agricultural chemical technologies for sustainable production. GPA has made previous submissions detailing a best practice approach to environmental exposure assessments[14]. It is important that legislations recognises that farming systems may change in time reflecting better practice and assessment should consider the current industry best practice standards.

For example, GPA supports APVMA use of distributions for real-world rainfall and river flows for runoff modelling which will now allow significant refinement to aquatic exposure assessments and the use of data libraries, which have been developed for dryland cropping regions in Australia. GPA believes that the credentials of current grains industry best practice using both no-till and stubble retention as the dominant farming practice today should be recognised within the baseline assessment methods used by both the APVMA and Department of Environment.

GPA requests the APVMA reconsiders its approach to recognising current industry best practice in making decisions under the legislation, using no-till and stubble retention as standard grains industry practice and also include these practices as the default for any regulatory consideration of industry or

[14] GPA response to call for public comment on proposed new APVMA framework for environmental exposure assessment.

commercial permits, labels or reviews related to Aquatic Exposure Estimates in Australian Pesticide Environmental Runoff Risk Assessment.

Theme 3: Compliance and enforcement

- *Whether the amendments have improved compliance and enforcement.*

Amendments from the 2013 Act appear to have had limited change in outcomes of compliance and enforcement. While GPA is aware that the AMPVA has been proactive with registrants on managing product safety and compliance for sale and use, results supplied through the National Residue Survey[15] have indicated that grain industry compliance with pesticide use and managing chemical maximum residue compliance and food safety for trade and export has been maintained at around 99.8% compliance. Adverse spray drift events unfortunately continue, however industry improvement in stewardship this has been slowed by delays in finalisation of the APVMA spray drift review and implementation of the proposed stage 2 program incorporating label reference and producer access to a spray drift management tool provided by the APVMA.

- *Whether, as a legislative priority, AgVet legislation should be aligned with the Regulatory Powers (Standard Provisions) Act 2014.*

Aligning AgVet legislation with the Regulatory Powers (Standard Provisions) Act 2014 would potentially improve the current monitoring and investigation powers to search and seize evidential material as well as inspect, examine, measure and test anything on the premises, as well as enforcement provisions through use of civil penalty provisions, infringement notices, enforceable undertakings and injunctions. However the resourcing of capacity to deliver impact from these powers would be a significant undertaking and costly exercise to implement. Such an alignment of regulatory powers should not be funded through the registrant cost recovery funding and levies and should therefore be manage through separate government appropriations.

- *Whether the AgVet Code should be simplified through greater use of conditions of registration to regulate the labelling of chemical products, and less reliance on specific labelling offences.*

There are significant risks to a more liberal approach through the use of conditions of registration to regulate the labelling of chemical products, rather than reliance on specific labelling offences. This is also complicated by the significant variance in state government control of use legislation across the commonwealth. GPA in a previous submission to the AgVet Chemical Task Group[16] has identified risks from the use of agricultural chemicals on a commodity or situation that is not listed on the APVMA approved label or permit.

GPA does not support the use of agricultural chemicals in grain commodities or situation that is not listed on the APVMA approved label or permit. The proposed control of use guidelines will potentially increase investment market failure for registrant interest in supporting crop protection needs of the grains industry in minor commodities and also compromise the ongoing legal support of APVMA in providing permit approvals:

- The proposed ACTG approach will potentially reduce multinational chemical company confidence for investment into Australia; reduce commercial company interest in Australia through potential increased of off-label use and resulting stewardship risks, particularly for new products, which Australia clearly seeks. This increased risk profile will also potentially further reduce Australia's ranking for investment priority which has historically been based on a robust regulatory and industry stewardship program, while competing with investment opportunity in Asia and South America where return on investment is higher.
- GPA believes the proposed approach to off label use could put the APVMA where a permit is requested by the grains industry or an individual business to be in a position of contravention

[15] http://www.agriculture.gov.au/ag-farm-food/food/nrs
[16] GPA Submission to AgVet Chemical Task Group (ACTG) national harmonisation of off-label use proposal - 28th February 2018.

of the current AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995 - REG 57 [17] where it states 'Subregulation (2) applies to the issue by the APVMA of a permit on application for a person to do, or omit to do, any thing which would, apart from the permit, be an offence against an eligible law of this jurisdiction', Part 7 of the AgVet Code[18] provides that the APVMA may issue permits, allowing a person to do something or omit to do something in respect of an active constituent for a proposed or existing chemical product, or in respect of a chemical product, that would otherwise be:

  - an offence against certain provisions of the AgVet Code
  - an offence against the provisions of a law of a jurisdiction declared by a law of that jurisdiction to be an eligible law for the purposes of the AgVet Code or the AgVet Code Regulations
  - a contravention against certain civil penalty provisions of the AgVet Code.

- The proposed ACTG proposal for off-label harmonisation would result in the APVMA being unable to legally under the current Federal legislation[19] to issue a permit for domestic use of a minor crop, even if part of the industry requires this for consumer confidence or discretionary request of a domestic market, such as Australian supermarkets as there would be no legal basis for this requirement.

GPA believes the proposed ACTG approach would ultimately be a more expensive option for the grains industry to implement for minor commodities through the ongoing cost of residue testing through whole of industry managed QA programs. Minor and emergency use in the grains industry has been very effectively managed through the APVMA permit program. GPA sees the ACTG off-label use proposal as a shifting of costs and responsibility from state and federal government to industry. The robust assessment through the permit program has ensured ongoing domestic consumer and export market confidence in Australian grain products.

- *Whether more measures should be included in disallowable legislative instruments made by the APVMA.*

The increased use of disallowable legislative instruments by the APVMA would be a good step forward for a science-based regulator that takes into account the best global knowledge on new technologies. While Parliament would still have powers to disallow APVMA regulations, this approach would increase the flexibility and responsiveness to rapidly evolving technologies such as digital and automation technologies currently being considered for use by industry.

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 a need for further 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. Use of disallowable legislative instruments by the APVMA in this case would be an appropriate step forward until state control of use legislation can catch up. 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.

Theme 4: Improve consistency in data protection provisions

- *Whether the amendments have improved data protection and made the associated provisions easier to understand.*

GPA in previous submissions has proposed new incentives including options to reform data protection to address the significant issue of investment market failure of AgVet investment in Australia. The

[17] http://classic.austlii.edu.au/au/legis/cth/consol_reg/aavccr1995491/s57.html
[18] https://apvma.gov.au/node/984
[19] https://www.legislation.gov.au/Details/C2016C00999/Download

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 since implementation of the 2013 Act 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 would support the Australian government to engage 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.

- *Whether Part 3 of the AgVet Code should be omitted to allow stakeholders to rely on commercial arbitration legislation for persons to negotiate access to both protected information and information with limits on its use.*

GPA does not support this approach as this would potentially lead to registrant uncertainty of maintaining CCI and data protection and a consequential loss of investment confidence in commercialising new AgVet technology in Australia. This could also significantly increase legal costs to registrants of defending and maintaining labels to data protected products. This cost would ultimately be borne by producers as end users.

- *Whether 'protected information' and 'information with limits on its use' should be consolidated.*

GPA did not support the *protected information' and 'information with limits on its use'* legislative reforms in the 2013 Act. There is a need for incentives to reflect the amount of effort or cost to deliver technology for some industries. There is also a need for incentive benefits that stretch data protection out to 3 to 5 years to be a higher bar of effort. There is also a need for additional limitation or protection period for the use of a chemical product on each entire crop or animal commodity group,

supported by the relevant industry through an identified priorities list. Incentives must be linked in the legislation to a list of industry priorities.

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.

Theme 5: Legislation improvements

- *Whether the simplification and re-organisation of provisions has helped them to better understand the legislation.*

While the 2013 Act has continues to try and address improved understanding and clarity of legislative provisions, changes have continued to create uncertainty, which has been very concerning when this has impacted on confidence of investment in meeting Australia's crop protection and animal health needs. For example, the 2013 Act introduced an alternative pathway to Category 25 applications [Part 2 Division 3 Section 27 Applications (2) (a)] which would allow third parties to apply to vary a product label with the consent of a registrant. What is unclear in the 2013 Act reforms is whether the data submitted would attract any data protection. If it does who gains the benefit, the data provider or the registrant giving consent? If there is no data protection then this needs to be clear in the legislation to avoid any confusion. The potential for data protection would provide significant incentive for greater investment by commercial manufacturers in this program and this would result in an increased number of permits being transferred to label registrations.

- *Whether the redrafting of existing 'legislative tests' into the four 'meets the X criteria' tests in subsection 3(1) of the AgVet Code has assisted them to comply with safety, trade, efficacy and labelling criteria.*

GPA is committed to further discussion with the Australian government and the APVMA to maintain environmental credentials for the grains industry while delivering safe and effective agricultural chemical technologies for sustainable production. GPA has made previous submissions detailing a best practice approach to environmental exposure assessments[20]. It is important that legislations recognises that farming systems may change in time reflecting better practice and assessment should consider the current industry best practice standards. GPA suggests that legislation recognises industry best practice such as the grains industry using no-till and stubble retention as standard industry practice and includes these practices as the default for any regulatory consideration of industry or commercial permits, labels or reviews.

The reforms to legislative tests have not addressed the key issue of a lack of investment in new active products to comply with safety, trade, efficacy and labelling criteria. The issue is that investment in new applications cannot be addressed through regulation, but rather requires incentives to facilitate fast tracked investment into Australia. 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

[20] Response to call for public comment on proposed new APVMA framework for environmental exposure assessment.

- 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[21] 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.

Theme 6: Variations to relevant particulars and conditions

- The value and practical effects of having multiple processes for varying relevant particulars and the effectiveness of existing processes for varying conditions, and whether there should be a streamlined means of varying conditions (recognising the technical assessment that can be required).

The value and practical effects of having multiple processes for varying relevant particulars is best demonstrated in the grains industry through industry initiated discussion with registrants and the APVMA in managing risks of adverse spray drift events from 2,4-D herbicide. Through discussion of all stakeholders, the APVMA has been able to vary conditions resulting in a positive outcome for producers resulting in significant reduction in spray drift risk. GPA has also recently supported Agvet 2018 Bill reforms 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.

- Whether AgVet legislation could be simplified by dealing with variations to approval and registration as new approvals and registrations.

GPA does not support dealing with variations as a new registration, as many existing older products which have been on the market for many years while only requiring only a minor label variation could be potentially required to re-submit major data sets and meet new regulatory requirements which did not exist at the time of registration. This in effect would discourage any label variations for product use improvement and would result in disinvestment by registrant in older generic off-patent products.

- What mechanisms would stakeholders support for dealing cost-effectively with incorrect information in notifiable variations and prescribed variations?

GPA supported the recent 2018 AgVet Bill reforms delivering options to implement computerised decision-making (Part 4 of Schedule 1), providing for internal review of an APVMA decision that is substituted for a computer-based decision, by providing for the APVMA to use computerised decision-making. This could be extended to more efficiently manage cost-effectively with incorrect information

[21] https://www.legislation.gov.au/Details/C2013C00545

in notifiable variations and prescribed variations. GPA in its previous submissions suggested that these reforms should go further, highlighting the need for further 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.

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;

Supported through legislation, 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;

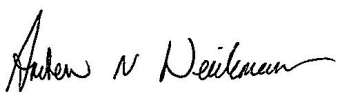
- Delivering cost savings, which would need to be based on co-equivalence of cost recovery models for evaluation
- Delivering technology to agricultural industries faster
- Increasing international confidence of Australia as a cost effective investment option.

GPA commitment to further reform discussion

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



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