



SUBMISSION

GPA response to the Senate Standing Committees on Rural and Regional Affairs and Transport enquiry on the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

Addressed to:

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GPA response to the Senate Standing Committees on Rural and Regional Affairs and Transport enquiry on the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

Thank you for the opportunity for Grain Producers Australia (GPA) to provide a response to the **Senate Standing Committees on Rural and Regional Affairs and Transport enquiry on the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)**¹.

Executive Summary

GPA provides the following response to the Senate Standing Committee Review. Further clarification of the rationale behind these positions is contained within the body of the submission.

Glyphosate: On the basis of international recognised regulation assessments, GPA supports the continued label registration and use of glyphosate products. *A loss of glyphosate in the agricultural production system would result in an annual loss of global farm income gains of US \$6.76 billion (AUS \$9.39 billion).*

Best Practice: United Nations programs highlight that industry participation and defined responsibility across the life cycle, including cost recovery policies and systems as well as the incorporation of sound chemicals management into corporate policies and practices as being a key element of best practice regulation.

Support for the current review process: GPA considers the current independent APVMA chemical review nomination process is independent and robust, with many examples of scientific reviews resulting in suspension of product registrations or changes to label use. The Australian government and its regulators APVMA and FSANZ are an integral part of global chemical safety review programs including the Codex Alimentarius program providing transparent internationally recognised decision making.

Timeframe for chemical reviews: GPA considers that the current timeframe for chemical reviews do not meet industry and community expectations. The relocation of the APVMA to Armidale has clearly impacting on its ability to deliver timely assessment outcomes, not only for registration of new chemical products but also ongoing review of prioritised chemicals. It underscores the importance of not allowing politics to interfere with the efficient operation of key regulatory bodies.

Investment market failure: A need for further legislative reform has been clearly demonstrated. Incentives must be put in place to encourage investment, which will support the delivery of technology. Access to which will provide significant, positive outcomes for Australian agriculture including grain growers. GPA has made a number of previous submissions proposing incentives to address the issue of significant market failure for AgVet chemical investment in Australia. These options are again detailed in this submission.

¹ https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Rural_and_Regional_Affairs_and_Transport/APVMA

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 provides the following responses to the questions raised in the Senate Standing Committee review.

a. The responsiveness and effectiveness of the APVMA's process for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators.

GPA response: It is important APVMA reviews are based on science-based evidence where adverse events or new international scientific evidence calls for reconsideration of existing chemical actives. GPA supports the APVMA in delivery of the current science based chemical review process as defined in the current legislation and regulations. GPA notes that following the classification of glyphosate as a 'probable carcinogen' by the International Agency for Research on Cancer (IARC) in 2015², the APVMA self-nominated glyphosate for reconsideration and commissioned an assessment of the IARC report by the Department of Health Office of Chemical Safety.

² <https://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf>

GPA notes the APVMA, following the IARC assessment, “considered glyphosate and found no grounds to place it under formal reconsideration”³. GPA notes all independent, science-based regulatory agency globally (including; Germany, New Zealand⁴, Canada⁵, the US⁶ and the EU^{7,8}) have comprehensively evaluated glyphosate and found it safe to use in accordance with label directions. GPA also notes the European Chemicals Agency (ECHA) conducted a hazard-based assessment of glyphosate in 2017, similar to that conducted by IARC, concluding, “No hazard classification for carcinogenicity is warranted for glyphosate”.

It is on this basis of all these international recognised regulation assessments that GPA supports the continued label registration and use of glyphosate products.

GPA has significant concern with the bias evidenced by the selective inclusion and exclusion of scientific data by the IARC panel assessing glyphosate. Our concern is well founded and supported by reports by Reuters⁹, noting the “removal of multiple scientists' conclusions that their studies had found no link between glyphosate and cancer in laboratory animals”.

The global impacts from a loss of glyphosate used in farming would cause significant economic, food supply and price impacts. A recent paper on the contribution of glyphosate to agriculture and potential impact of restrictions on use at the global level found;¹⁰,

First round' impacts are the loss of farm level and aggregate impacts associated with the widespread use of GM herbicide technology crops (tolerant to glyphosate). There would be an annual loss of global farm income gains of US \$6.76 billion (AUS \$9.39 billion) and lower levels of global soybean, corn and canola production equal to 18.6 million tonnes, 3.1 million tonnes and 1.44 million tonnes respectively. There would be an annual environmental loss associated with a net increase in the use of herbicides of 8.2 million kg of herbicide active ingredient (C 1.7%), and a larger net negative environmental impact, as measured by the environmental impact quotient (EIQ1) indicator of a 12.4%. Also, there would be additional carbon emissions arising from increased fuel usage and decreased soil carbon sequestration, equal to the equivalent of adding 11.77 million cars to the roads.

World prices of all grains, oilseeds and sugar are expected to rise, especially soybeans (C 5.4%) and rapeseed (C 2%). The welfare impacts are mostly negative, with global welfare falling by US \$7,408 million (AUS \$5.33 billion) per year. Land use changes will arise, with an additional cropping area of 762,000 ha, of which 53% derives from new land brought into cropping agriculture, including 167,000 of deforestation. These land use changes are likely to induce the generation of an additional 234,000 million kg of carbon dioxide emissions'.

GPA considers the current independent APVMA chemical review nomination process is independent and robust, with many examples of scientific reviews resulting in suspension of product registrations or changes to label use, including:

³ <https://apvma.gov.au/node/13891>

⁴ <https://www.epa.govt.nz/assets/Uploads/Documents/Everyday-Environment/Publications/EPA-glyphosate-review.pdf>

⁵ <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-re-evaluation-decisions/2015/glyphosate/document.html>

⁶ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073>

⁷ <http://www.efsa.europa.eu/en/efsajournal/pub/4302>

⁸ <https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa>

⁹ <https://www.reuters.com/investigates/special-report/who-iarc-glyphosate/>

¹⁰ Graham Brookes, Farzad Taheripour & Wallace E. Tyner (2017): The contribution of glyphosate to agriculture and potential impact of restrictions on use at the global level, GM Crops & Food, <https://doi.org/10.1080/21645698.2017.1390637>

- 2011 - Suspension of the use the insecticide products containing dimethoate and issue of new label instructions that no longer allow the use of dimethoate on specified food crops. This reconsideration process was finalised in October 2016.
- 2014 - Cancellation or variation to all registered uses of products containing fenthion, leading registrant cancelling all remaining registered products which were removed from the market as a result.
- 2018 - Following incidents of spray drift crop damage in December 2017, the APVMA suspended all registered labels for products containing 2,4-D and issued new label instructions in 2018.

b) The funding arrangements of the APVMA, comparisons with equivalent agricultural chemical regulators internationally and any impact these arrangements have on independent evidence-based decision making.

GPA response: Over eighty percent of APVMA's total expenditure of \$39.9 million in 2018/19 was cost-recovered from industry, including application fees, annual fees and registrant levies.¹¹ GPA notes that this approach to funding of the regulatory program is considered global best practice.

Under the United Nations Environment program, the Strategic Approach to International Chemicals Management (SAICM), adopted by the First International Conference on Chemicals Management (ICCM1) on 6 February 2006 in Dubai, is a policy framework to promote chemical safety around the world. An SAICM document details orientation and guidance for achieving the 2020 goal of sound management of chemicals¹². This document details that; *"countries should take measures to further encourage industry involvement, including the development of policies on the responsibilities of the industry sector and national administrations, and should develop financial solutions and appropriate mechanisms and economic instruments including cost recovery systems. All those involved in national planning processes must internalise the costs and integrate the economic benefits of providing resources for sound chemicals management. In doing so, they should include the rationale for mainstreaming and the development of capacity for assessing the costs of inaction and benefits of action on chemicals issues at the national, regional and global levels"*. This internationally recognised standard for best practice highlights that the current financial solutions of cost recovery and the levy based system for registrants reflects global best practice.

The Quick Start program, administered by the United Nations Environment Program has conducted an impact evaluation review¹³ on implementation of best practice for chemical regulation, particularly focused in developing countries. The Strategic Approach to International Chemicals Management (SAICM) is a policy framework to promote chemical safety around the world. A main driving force for the establishment was the recognition of the gaps between the capacities of different countries to manage chemicals safely. SAICM has as its overall objective the achievement of the sound management of chemicals and hazardous wastes throughout their life cycle so that, by 2020, chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment. This "2020 goal" was adopted by the World Summit on Sustainable Development in 2002 as part of the Johannesburg Plan of Implementation.

¹¹ https://apvma.gov.au/sites/default/files/images/apvma-annual-report-2017-18-tagged_0.pdf

¹² SAICM Document - 29 June 2015 Overall orientation and guidance for achieving the 2020 goal of sound management of chemicals <http://www.saicm.org/Portals/12/Documents/OOG%20document%20English.pdf>

¹³ Quick Start Programme Impact Evaluation Final Report 21 September 2015
<http://www.saicm.org/Portals/12/Documents/QSP/QSP%20Impact%20Evaluation%20Report.pdf>

The following set of 11 basic elements has been recognized as critical at the national and regional levels to the attainment of sound chemicals and waste management, namely:

- i. Legal frameworks that address the life cycle of chemicals and waste;
- ii. Relevant enforcement and compliance mechanisms;
- iii. Implementation of relevant international multilateral environmental agreements, health, labour and other relevant conventions as well as voluntary mechanisms;
- iv. Strong institutional frameworks and coordination mechanisms among relevant stakeholders;
- v. Collection, and systems for the transparent sharing of, relevant data and information among all relevant stakeholders using a life cycle approach, such as the implementation of the Globally Harmonized System of Classification and Labelling of Chemicals;
- vi. Industry participation and defined responsibility across the life cycle, including cost recovery policies and systems as well as the incorporation of sound chemicals management into corporate policies and practices;
- vii. Inclusion of chemicals and waste in national health, labour, social, environment and economic budgeting processes and development plans;
- viii. Chemicals risk assessment and risk reduction through the use of best practices;
- ix. Strengthened capacity to deal with chemicals accidents, including institutional strengthening for poison centres;
- x. Monitoring and assessing the impacts of chemicals on health and the environment;
- xi. Development and promotion of environmentally sound and safer alternatives.

This United Nations program highlights industry participation and defined responsibility across the life cycle, including cost recovery policies and systems as well as the incorporation of sound chemicals management into corporate policies and practices as being a key element of best practice regulation. Other nations are clearly being encouraged to pursue cost recovery system such as that used by the APVMA.

GPA supports the current approach to cost recovery under current legislation. The quantum of cost recovery should be sufficient for the APVMA to deliver effective and timely review of label applications and permits. GPA would support an increase in Federal government funding for independent chemical review by the APVMA through budget appropriation. This would offset the cost to registrants through levies, the cost of which is ultimately borne by producers.

GPA in February 2014 made a submission¹⁴ to the Department of Agriculture First Principles Review of Cost Recovery at the APVMA Consultation Paper¹⁵. In review of the First Principles Review of Cost Recovery at the Australian Pesticides & Veterinary Medicines Authority final report, GPA supported many of the recommendations for implementation of a cost recovery model at the APVMA, which recognises that a user pays system and equity of investment and return by commercial companies should be rewarded.

In general, GPA noted the final report considered a balanced outcome for community, industry and registrants. In particular, GPA noted there was a specific recommendation for additional government appropriation for public good outcomes, however this did not extend to chemical review. GPA in its submission stated that there are some aspects of APVMA activities including compliance, adverse event reporting, chemical review, informing policy, general research, website maintenance, reporting

¹⁴ Grain Producers Australia submission to First Principles Review of Cost Recovery at the APVMA Consultation Paper February 2014.

¹⁵ First Principles Review of Cost Recovery at the APVMA Consultation Paper November 2013.

and stakeholder consultation which require independence by the regulator and which require adequate funding for delivery regardless of seasonal impacts on sales or company investment in registrations. GPA sees a clear need for government appropriation in these programs as is the case with Australia's major agricultural competitors including Canada and the USA.

While the report recommended these public good activities should be funded through government appropriation, the recommendations did not extend to chemical review. As stated in the previous submission, GPA recognises there are some aspects of APVMA activities that require independence in evaluating risks and impacts of pesticide and veterinary medicines and it is difficult to see this independence can be adequately maintained and resourced when considering the seasonal impacts of pesticide sales and revenues from registrations which will impact on resourcing of APVMA chemical review delivery. There should be reconsideration of the need for increased independent funding for chemical review with increased funding for APVMA chemical review delivered through government budget appropriation..

GPA noted the report contained the following recommendations and supports the following:

- Implementation of up-front fees for activities where the direct costs can be reasonably attributed to a specific user of the service, such as the costs of assessing applications for product registration. To reduce the impact of the up-front fees on applicants, for fees above a threshold limit, applicants should have the option to either pay the full fee up-front or pay by installments with a fee adjustment to reflect the cost of administering the installment payment arrangement.
- Fee exemptions where partial or full subsidisation of fees is necessary to prevent perverse outcomes. Specifically, GPA supports subsidisation of the application fee and pre-application advice sought for minor and emergency use permits in order to support the intent of these programs. As previously stated there are multiple beneficiaries of minor and emergency use permits, including the consumer and contribution to preventing catastrophic industry loss impacting on Australian GDP.
- Support for an annual flat levy for each activity where it is not practical to attribute individual costs, such as compliance monitoring, investigation, enforcement and other general activities. Also support for tiered levies based on the value of agvet chemical product sales during the preceding year to recognise the need to assist the continued supply of products, particularly those with low levels of sales.
- Support for increased of government funding for the APVMAs activities in informing policy in accordance with the principle of the Cost Recovery Guidelines for costs not directly related to the provision of products or services.
- Support for maintenance of the APVMAs financial reserve to support financial viability in managing short term fluctuations in the level of activity influenced by seasonal variability.
- Support for regular monitoring and adjustment of fees and charges in line with changes in expenditure rather than automatic indexation.

In relation to minor use permits the report recommends applicants only pay a portion of the assessment cost. GPA supports this recommendation and notes the *"application fee should be set at a level that balances the ability for the APVMA to recover a portion of the cost of assessment upfront while not acting as a significant disincentive for users to seek a minor use permit for off-label use of an agvet chemical."*

Given the quantum of fees for the minor use program proposed under a fully cost recovered funding model, any increase in fees would be damaging to productivity and sustainability of the grains industry. Minor use and emergency permit fees should be maintained as they currently are.

GPA proposes that continued government appropriation is required to provide effective support to a cross industry, RDC led initiative in minor use which has initially been funded through the Australian

Government Department of Agriculture program; A Competitive Agriculture Sector - improved access to agricultural and veterinary chemicals.

GPA has previously reviewed a detailed economic analysis of the full impact of proposed cost recovery changes to GRDC and HAL minor use programs. This analysis details studies in Australia, which indicate benefits of minor use permits from 13:1 to 95:1. This analysis based on HAL and GRDC minor use investment clearly identifies that moving to a full cost of recovery model would be detrimental to producers and the Australian Economy. The loss of benefit would be between \$349 million and \$11 billion over 3 years. Any change to the current cost recovery arrangements would clearly have an adverse impact on the GRDC research programs being able to effectively deliver outcomes to the grains industry.

Agriculture including the grains industry is facing current productivity challenges, which will significantly increase within the next decade. Grains, horticulture, viticulture and animal industries are facing significant emerging Biosecurity threats and impact of pesticide resistance. Unfortunately, Australia is experiencing increasing market failure with regards investment in agricultural pesticides and veterinary medicines. To meet multi-cultural consumer demand for an increasing diverse range of foods, a cost recovery model supporting effective, cost efficient delivery of minor use and specialty needs of pesticide and veterinary medicines is required.

c. The roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals.

GPA response: GPA recognises the role various Federal government departments have in supporting the APVMA in its regulatory decision making processes. The Department of Health, Environment and the regulator FSANZ all have a role in this process. GPA has continued to have concern these external departments have struggled to ensure they have allocated adequate resources to deliver information and responses in a timely manner, therefore impacting on the time lines for the decision making processes of the APVMA. GPA is aware this has already occurred in addressing reduced support to the APVMA through the Department of Health's Office of Chemical Safety. GPA would support a model that brings these resources under one regulatory program within the APVMA.

It is important to recognise global chemical safety programs provide transparent and rigorous science based assessment. As detailed in FAO's Strategy for Improving Food Safety Globally¹⁶, the Codex Alimentarius program is the global process supporting science-based food safety governance and decisions. The Australian government and its regulators APVMA and FSANZ are integrally engaged in this program. The Codex Alimentarius is the compendium of internationally adopted standards, guidelines analysis and sampling methods, and codes of practices for food products, developed by the FAO/WHO Codex Alimentarius Commission, an intergovernmental organization created in 1963.

Codex coverage spans: general standards for food additives, hygiene and contaminants; commodity standards for several product groups; labeling; methods and analysis and sampling; food import and export inspection and certification; and nutritional aspects. Decisions are adopted by consensus based on the best scientific and technical knowledge available. Codex standards, though not mandatory until adopted into national legislation, are recognised under the WTO SPS agreement as the international reference/benchmark standards for food safety.

¹⁶ Efficient Agricultural and Food Systems Review of the implementation of FAO's Strategy for Improving Food Safety Globally
<http://www.fao.org/3/a-bd712e.pdf>

While an important part of FAO's work on food safety relates to Codex and thus falls within the scope of this evaluation, the Codex Alimentarius Commission is a joint body of FAO and WHO, has its own governing body, charter, strategy and operation plans and reporting structures.

GPA is also aware of private commercial investment in risk assessment models that would significantly speed up the efficiency APVMA regulatory decisions. These models are already used by commercial registrants to efficiently consider potential environmental terrestrial and aquatic impacts. There is a need to ensure the APVMA adopts and uses these types of tools to speed up regulatory evaluation as an alternative rather than an addition to existing processes.

d. The need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products.

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

As detailed in these previous submissions by GPA, it is recognised Australia is no longer on the global priority list for pesticide and veterinary medicine investment in commercialisation as it was 20 years ago. 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.

To remain internationally competitive it is essential Australian grain growers have access to the same pesticide technologies as other, often competing, overseas producers. It is essential unnecessary reviews and red tape does not further erode investment in Australian AgVet as this will negatively impact productivity through reduced technology access. GPA has previously identified 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, 2017 and 2018, 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 the 2014, 2017 and 2018 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.

There is clearly a need for further legislative reform to deliver technology access outcomes for Australian agriculture including grain growers. GPA has made a number of submissions proposing 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.

Table 1. Comparison of first registered labels between Australian and USA. (grains 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 , Tuberos & Corn 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; Tuberos & Corn 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

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 the last years.

e. The impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner.

GPA response: 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 survey found companies had at least a 12 month delay over and above statutory timeframes on several new chemical products. All companies had examples of at least one or more new product applications that had missed the 2017 season for growers as a consequence of the delays. The 2017 survey found that the grains industry had a delay in registration of at least 3 major new herbicide/fungicide actives resulting in a collective minimum direct loss through lack of the technology benefits these products deliver to grain growers of at least \$200 million and up to \$500 million, potentially compounding if pesticide resistance evolution that these new products resolve tracks faster than expected. Assessments had significantly slowed since November, particularly OH&S/Health and Environment.

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 on the survey of chemical companies conducted by GPA in May 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 delayed industry access for one season. At the time of the survey, the companies were anticipating this could be extended to a delay for 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 current situation on delays in new chemical mode of action products lasts for another 2 years with a delay of 12 months on major projects, particularly new mode of action herbicide and fungicide products, GPA estimates the minimum impact through lost productivity and accelerated pesticide resistance evolution to the grains industry would be well over \$1 billion. These estimates are based on the following;

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 impacts¹⁷ 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*

¹⁷ <https://grdc.com.au/resources-and-publications/all-publications/publications/2016/03/impactofweeds>

- *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 estimate of disease impacts were based on delays to a new MOA canola fungicide for blackleg control which is separately 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 figures¹⁸, 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 potentially losses of 58.9% and current losses in wheat of 16.4%¹⁹.*
- *Current losses from blackleg in canola is \$76.6 million and potential losses of \$331.3 million based on a crop value of \$500 million²⁰. Without an effective alternative new mode of action fungicide for blackleg control, based on current resistance development to existing 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 the estimates previously detailed in the 2017 submission were conservative and could easily be higher than these estimates.

GPA considers the current timeframe for chemical reviews do not meet industry and community expectations. The relocation of the APVMA to Armidale has clearly impacted its ability to deliver timely assessment outcomes, not only for registration of new chemical products but also ongoing review of prioritised chemicals. The GPA believes it is imperative the APVMA is provided with the funding and resources to ensure it can put in place the staff required to reduce the timeframes.

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 the delay situation 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.

f. Other related matters – Addressing market failure of investment in new chemical product for agriculture in Australia.

GPA response: 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

¹⁸ https://grdc.com.au/_data/assets/pdf_file/0025/204748/disease-loss-barley.pdf.pdf

¹⁹ https://grdc.com.au/_data/assets/pdf_file/0026/203957/disease-loss-wheat.pdf.pdf

²⁰ https://grdc.com.au/_data/assets/pdf_file/0021/82641/grdcreportdiseasecostoilseedspdf.pdf.pdf

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 things 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 in 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 %) if the use qualifies as a priority identified by producer industries.

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.

GPA supports the government current engagement 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. These incentives must however 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 Forum²¹ established this process and manages a current list of industry priorities and needs²². 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 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.

GPA has reviewed the current exposure draft for the next tranche of AgVet legislation reforms. GPA recognises there is intent to increase incentives for investment through revised data protection models. However, while the intention of this legislative change is to reduce market failure, in effect the current proposal is likely to make market failure worse and more importantly, it will be hard to wind back the commercial impacts once implemented.

²¹ <https://www.agrifutures.com.au/wp-content/uploads/publications/17-019.pdf>

²² <https://www.agrifutures.com.au/national-rural-issues/agvet-chemicals/>

GPA has previously suggested a number of incentive reforms that are 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 onto label being rewarded with acceleration of an alternate registrations 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
- Increased Federal Government support and legislative incentive to build on the AgVet Collaborative Forum - now established cross agricultural industry minor use program known as the broadly 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.
- 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.

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.

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.

GPA commitment to further reform discussion

As detailed in previous submissions by GPA, agriculture is facing significant challenges and must have access to all the necessary tools 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.

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 in this submission further in detail, please contact me

Yours sincerely

Andrew Weidemann
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