

GRDC submission to the ACIL Allen review of the operation of amendments to legislation made by the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013.

Thank you for the opportunity for the Grains Research and Development Corporation (GRDC) to provide a response to the ACIL Allen review of the operation of amendments to legislation made by the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013.

Summary:

The operation of the amendments to legislation made by the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013 has generally been seen by GRDC as effective. Improvements can be made in:

- a) Utilisation of overseas data and assessments for residue, efficacy and crop safety assessments
- b) “Shut the gate” provisions on data submission to take into account seasonality of crops
- c) Altering provisions on fit and proper persons tests for permits
- d) Reimplementing incentives for inclusion of minor use crops in primary submissions

About the Grains Research and Development Corporation

GRDC was established in 1990, under the then Primary Industries and Energy Research and Development Act 1989 (PIERD Act), as a transparent accountable entity to fund and administer the levy into RD&E to increase the profitability of the grains industry in Australia. As a result of amendments made in December 2013, that Act is now known as the Primary Industries Research and Development Act 1989 (PIRD Act).

The PIRD Act provides for the funding and administration of primary industries R&D to:

- increase the economic, environmental and social benefits to members of primary industries and to the community in general by improving the production, processing, storage, transport or marketing of the products of primary industries
- achieve sustainable use and management of natural resources
- make more effective use of the resources and skills of the community in general and the scientific community in particular
- support the development of scientific and technical capacity
- develop the adaptive capacity of primary producers
- improve accountability for expenditure on R&D activities in relation to primary industries.

GRDC's investment activities are supported by funds from both grain growers and government and is administered under a Statutory Funding Agreement (SFA) between GRDC and the Commonwealth of Australia. A copy of the agreement is available on the GRDC website (www.grdc.com.au).

Through the agricultural levy system Australian grain growers impose a levy on themselves to support R&D.¹ Section 5 of the PIRD Act allocates these levy funds to GRDC in order for it to undertake its statutory purpose. Grain growers have agreed to a levy of 0.9% of farm gate value on 24 crops including wheat; coarse grains—barley, oats, sorghum, triticale, millets/panicums, cereal rye and canary seed; pulses—lupins, field peas, chickpeas, faba beans, vetch, peanuts, mung beans, navy beans, pigeon peas, cowpeas and lentils; and oilseeds—canola, sunflower, soybean, safflower and linseed. Maize is also levied but at a rate of 0.693%.

¹ Department of Agriculture and Water Resources (2009) ‘Levy Principles and Guidelines’.

Grower contributions are matched by the federal government up to 0.5% of the value of GVP based on a three-year rolling average. In 2017-18 grower contributions were \$117.3 million and government contributions were \$71 million with over \$192 million spent on RD&E to benefit Australian grain growers.

GRDC strategic purpose is:

To invest in Research, Development and Extension to create enduring profitability for Australian Grain Growers.

Australian grain growers aim to achieve sustainable profit by adopting the outputs of GRDC's investments in RD&E. The focus on enduring profitability is important to achieving the statutory objectives of GRDC's enabling legislation.² It is only at the point at which a grain grower adopts the new technologies, tools and practices made available through GRDC's investment in RD&E that spill over benefits associated with this investment are realised. Some of the spill over benefits include:

- Improved economic and social outcomes in rural and regional communities.
- Improved environmental management underpinned by sound RD&E.
- Enhanced contribution to the broader Australian economy.

Operationally GRDC invests in RD&E portfolio that addresses profitability constraints and opportunities spanning temperate and tropical cereals, coarse grains, pulses and oilseeds. This involves coordinating and investing in RD&E initiatives; monitoring, evaluating and reporting on their impact; and facilitating the dissemination, adoption and commercialisation of their results.

GRDC invests approximately \$1,000,000 annually in generating data for submission for registration, variation or permitted use of agricultural chemicals. This investment is done usually with a similar or greater investment with a registrant.

² *Primary Industries Research and Development Act 1989.*

a <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/growers-commercial-users/user-requested-minor-use.html>

period (for the use of a chemical product on each entire crop or animal commodity group), this should only be allowed where the group priority is supported by the relevant industry through an identified priorities list.

Incentives must be linked in the legislation to a list of industry priorities. Reference to a list of industry priorities by the government should include the list delivered through the successful AgVet Collaborative Forum, currently supported by all plant industry RDCs. A project and report funded by the Department of Water Resources through AgriFutures Australia, 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 processes from the USA Inter-regional Research Project #4 (IR-4 Project) minor use program. Like these North American programs, the Australian Government should consider additional financial incentives to underwrite an Australian minor use program such as fee waivers and discounts, particularly where generic compounds are involved. The intention from this legislative change is to reduce market failure, but in effect the proposal is likely to induce further market failure and more importantly, it will be hard to wind back the commercial impacts once implemented. GPA has previously suggested several incentive reforms likely to address market failure without resulting in any additional cost to the government or regulators. These include;

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

Also, in the 2014 submission on Streamlining Regulation of Agricultural and Veterinary Chemicals, the Hort Innovation Australia (HIA) proposed the following:

In terms of the proposed extensions to limitation and protection periods Hort Innovation would encourage DAWR to review the minor use incentive provisions of the regulations associated with the Canadian *Pest Control Products Act* (<http://laws-lois.justice.gc.ca/eng/acts/P-9.01/>). As with the current limitation and protection periods in 34M of the Agvet Code in Australia, the exclusive protection period in Canada is 10 years from the date of first registration. However, that protection can be extended by one year for each three eligible minor use crops added to a label, up to a maximum of five additional years (*Regulations Amending the Pest Control Products Regulations*). In seeking the additional years of exclusive protection, a Canadian registrant application must provide evidence of support from users and federal and provincial agriculture authorities and the minor uses would, generally, have been part of the Canadian minor use priority list. The extensions only apply to residue data and apply only to the crops tested. If representative crops are tested the maximum number of eligible minor uses in the crop group will be the number of representative crops. If such a system were to apply in Australia and a registrant sought to gain extended data protection by seeking to register in Assorted Tropical and sub-Tropical crops, which contains 39 crops, doing residue trials in avocados, bananas and mangoes, they would gain one additional year as these are the three representative crops for the crop group.

Hort Innovation feels that possible extensions to protection periods should be coupled with additional registrant incentives such as fee waivers and discounts, particularly where generic compounds are involved. In Canada, the fees for a residue data assessment can be \$15,838 with a processing fee of \$1,133. In the Canadian regulations a User Requested Minor Use Label Expansion (URMULE^a) is exempt other than a processing fee of \$247. Under this approach, an application would not be charged a fee if the proposed label extension fell within the URMULE category. The registrant would pay a relatively small processing fee for the label change. From an Australian perspective such an approach would be of great value particularly when as it would lessen the cost for situations involving individual crops or where data protection extensions may be considered of little commercial value to registrants, e.g., use of generic compounds in minor crops.

^a <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/growers-commercial-users/user-requested-minor-use.html>

Theme 1: Application assessment efficiency and effectiveness

The amendments to increase the use of overseas data and assessments from other regulators was welcomed by the GRDC. To ensure greater utilisation of this amendment, the GRDC requests a guidance document provided by the APVMA on applicability / acceptability / merit of overseas data and assessments. In particular, the GRDC seeks clarification on when the APVMA will accept overseas residue, efficacy and crop safety data as deemed equivalent in the use pattern and Good Agricultural Practice (GAP) to Australian use patterns and GAP. This could be to provide bioequivalence regions, such as provided in Europe, or measures of confidence details required to determine equivalency between data sets. A report commissioned by GRDC concluded that there were no patterns of response in relation to climatic covariates. This Report indicated that, for at least efficacy, there should be no limitation on use of overseas data.

Theme 2: Reconsiderations (chemical review)

The amendments to increase timeliness and certainty to reconsiderations by implementing “shut the gate provisions” were welcomed by the GRDC. However, the GRDC is concerned that the APVMA, when determining the prescribed limits for data submission, may not consider the seasonality of the use patterns in question. If additional data are required, there may be limited, if any, opportunity for the production industry to generate data for the reconsideration, due to the seasonality of crops.

Theme 3: Compliance and enforcement

There appears to be an anomaly in the compliance and enforcement section of the Amendment Act in relation to the fit and proper person tests for permits. While the holder of a permit (minor use, emergency or research) is required to be assessed as fit and proper, the permit holder is rarely the user of the use pattern permitted under the permit. The requirement for a permit holder to be aligned to the Australian Government’s Spent Conviction Scheme (which provides that only convictions or penalty orders in the previous ten years need to be declared) appears to be over governance and has no operational compliance on who uses a chemical under a permit.

Theme 4: Improve consistency in data protection provisions

The amendment to improve data protection for data submitted through a permit application has been welcomed as providing incentives for both registrants and industry to invest in minor use data generation.

The GRDC and others wish for greater incentives for the registration of minor uses which may include increased data protection provisions for registration which include minor use patterns. It is of concern that the amendments include “removing provisions relating to data protection extensions for minor uses because they had never been used in the nearly ten years they had been included in the Agvet Code”, which is cited without context. These provisions were not able to be used due to other complexities in the AgVet code. There is a need for incentives for inclusion of minor uses which should include data protection extensions.

An incentive scheme would provide greater value to the Australian economy if additions of minor crops occurred with the primary application. This would provide Australian growers with new use patterns earlier and not cause unintended consequences of delaying the submission of minor use data packages. The proposed system, in providing additional protection times, is encouraged and supported. The method for determining the additional protection periods, however, is not balanced across crop groupings and could act as a disincentive for some minor use crops.

In the GRDC submission on Streamlining Regulation of Agricultural and Veterinary Chemicals, GRDC referred the inquiry to additional incentives put forward by the Grain Producers Australia (GPA) submission, which includes the establishment of a point credit system for registrants:

Reforms to the legislation do not link the proposed incentives to industry need or priorities. The proposal to limit extension of the protection period only if the application to vary an existing registration is made at least three years before the limitation or protection period for the information associated with the existing registration expires, will result in companies delaying decisions for support of minor crops and where market failure exists. Potential outcomes will be that chemical companies will potentially slow down investment in minor and new crops and data protection, the resulting effect will be a slowdown in the rate of industry access to new products, and will skew investment into crops that may not meet the gaps identified by industry. The incentives also don’t reflect the amount of effort or cost to deliver technology for some industries. There is a need for incentive benefits that stretch data protection out to 3 - 5 years to be a higher bar of effort than a single year of extension. While the proposed legislations recognises this with a proposed twelve months additional limitation or protection

^a <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/growers-commercial-users/user-requested-minor-use.html>

The GRDC will continue to engage with the Australian and state governments to improve the AgVet legislation to deliver productivity outcomes to agricultural industries and the Australian economy and community.

a <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/growers-commercial-users/user-requested-minor-use.html>