

**GRDC response to the invitation by the Senates Rural and Regional Affairs and Transport Legislation Committee (Committee) Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018**

## Summary

### **Proposal 1: Provisional registration of chemical products**

GRDC supports the intent of the proposed approach on reforms for the provisional registration of chemical products but has concerns that this may increase the expectations that the efficacy data package will be a co-investment between the registrant and industry as represented by Rural Development Corporations.

### **Proposal 2 – An accreditation scheme for assessors in the future**

GRDC conditionally supports the proposed approach to reforms on accreditation of assessors, with the need to ensure independence assessors and therefore the APVMA and provide liability limitations for assessors.

### **Proposal 3 – Prescribed approvals and registrations**

GRDC conditionally supports the proposed approach to reforms on prescribed approvals and registrations as the details of minimal technical risk are yet to be described in the regulations.

### **Proposal 4 – Data protection incentives for certain uses of chemical products**

GRDC supports the intent of proposed approach to reforms on data protection incentives for certain uses of chemical products with other incentives also be considered and the method for determining the period of additional protection needs to be reconsidered.

### **Proposal 5 – Prescribe certain information that can be taken into account if provided during an assessment**

GRDC supports the reforms on information that can be taken into account in determining applications.

### **Proposal 6 – Provide for computerised decision-making**

GRDC supports the proposed approach to reforms to modernise the Agvet Code by providing for the APVMA to use computerised decision-making.

### **Proposal 7 – Improve the transparency of voluntary recalls**

GRDC supports the proposed approach to reforms to improve the transparency of voluntary recalls.

### **Proposal 8 – Require relevant information to be provided in relation to label approvals and variations**

GRDC supports the proposed approach to reforms on notification of new information

### **Proposal 9 – Standards for registered chemical product constituents**

GRDC conditionally supports the proposed approach to reforms on standards for registered products as long as there is sufficient legislative mechanism to withdraw approvals where such changes result in adverse experience reports.

### **Proposal 10 – Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval**

GRDC supports the proposed reform on suspension or cancellation of approval or registration for provision of false or misleading information correcting a current anomaly.

### **Proposal 11 – Addressing an inconsistency in label particulars (**

GRDC supports the proposed reform on supply of registered chemical products with unapproved label to clarify label information.



**Proposal 12 – Improving dealings with suspended approvals and registrations**

GRDC supports the proposed reform on variation of approval or registration during suspension

**Proposal 13 – Address anomalies in matters that can be prescribed for the statutory criteria**

GRDC supports the proposed reform on safety, efficacy, trade and labelling criteria requiring that the APVMA must have regard to overseas data.

**Proposal 14 – Simplifying APVMA corporate reporting requirements (*annual operational plans*)**

GRDC conditionally supports the proposed approach to reforms on remove duplication of reporting where the corporate plan is adjusted annually and provides transparency on operational activities of the APVMA.

**Proposal 15 – Align the 2014 legislation review with the overarching review of agvet chemical legislation (*other amendments*)**

GRDC supports the proposed reform

**Proposal 16 – Make minor and machinery changes to the Administration Act and Agvet Code (*other amendments*)**

GRDC supports the proposed reform

**Proposal 17 – Other Amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016 (*other amendments*)**

GRDC supports the proposed reform



## 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](http://www.grdc.com.au)).

Through the agricultural levy system Australian grain growers impose a levy on themselves to support R&D.<sup>1</sup> 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%.

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 Purpose

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.<sup>2</sup> 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:

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<sup>1</sup> Department of Agriculture and Water Resources (2009) 'Levy Principles and Guidelines'.

<sup>2</sup> Primary Industries Research and Development Act 1989.



- 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.

## LEGISLATIVE PROPOSALS

### **Proposal 1: Provisional registration of chemical products**

GRDC supports the intent of the proposed approach on reforms for provisional registration of chemical products but has concerns that this may increase the expectations that the efficacy data package will be a co-investment between the registrant and industry as represented by Rural Development Corporations. There also could be increased request to continue with the Commonwealth AgVet Access grants to provide the data required. It would appear to be little efficiency gains in only having efficacy covered under a provisional registration. As indicated by the CropLife submission to the consultation, a registrant would unlikely bring a new product or use pattern to Australia without conducting trials under Australian conditions and that crop safety packages would be conducted in conjunction with efficacy trials. Rarely would a registration submission be held up due to the need to provide an efficacy data package. Grain Producers Australia proposed that provisional registration to also cover chemical residues, which GRDC would also support. There is a risk that under provisional registration that other use patterns are then developed outside provision registration label, with the expectation that the registration will be amended to incorporate these additional use patterns. This could impact on trade with residue violations and an additional burden on RDC's to conduct the efficacy and residue work to support these other use patterns.

### **Proposal 2 – An accreditation scheme for assessors in the future**

GRDC conditionally supports the proposed approach to reforms on accreditation of assessors, with the need to ensure independence assessors and therefore the APVMA and provide liability limitations for assessors.

Under the current system the assessors of the regulatory packages are not known to the registrants. Under the proposed system, an accredited assessor would be selected by the registrant. This may put undue pressure on assessors to approve data packages that are marginal in meeting the regulatory requirements. The independence of the regulatory system will be further questioned by the public and NGOs.

An alternative would be for accredited external assessors be allocated to registrants by the APVMA. This would allow for the assessor to maintain independence from the registrant and uphold the integrity of the registration systems.

Another alternative is to limit external assessments to areas of low risk particularly if this information has been assessed by risk based overseas regulators.

GRDC draws the inquiry to the GPA submission on concerns over the liability of the assessors and requirement for legislative instruments to provide a limitation of liability.

### **Proposal 3 –Prescribed approvals and registrations**

GRDC conditionally supports the proposed approach to reforms for prescribed approvals and registrations as the details of minimal technical risk are yet to be described in the regulations. GRDC wish to reiterate the concerns raised by GPA that under the current system of prescribed variations has resulted in some efficacy difference where formulation changes occurred. The APVMA requires to have legislative mechanisms to withdraw prescribed approvals and registrations where there have been adverse experiences.

### **Proposal 4 – Data protection incentives for certain uses of chemical products**

GRDC supports the intent of proposed approach to reforms on data protection incentives for certain uses of chemical products with other incentives also be considered and the method for determining the period of additional protection needs to be reconsidered.

GRDC refers the inquiry to additional incentives put forward by the GPA submission which includes the establishment of a point credit system for registrants.

The proposed system in providing additional protection times is encouraged and supported. The method for determining the addition protection periods however is not balanced across crop groupings and could act as a disincentive for some minor use crops.



An incentive scheme would provide greater value to the Australian economy if additions of minor crops occurred with the main 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.

**Proposal 5 – Prescribe certain information that can be taken into account if provided during an assessment**

GRDC supports the proposed approach to reforms on information that can be taken into account in determining applications. Where reforms can alleviate unnecessary delays to the registration and approval on new chemistry is support.

**Proposal 6 – Provide for computerised decision-making**

GRDC supports the proposed approach to reforms to modernise the Agvet Code by providing for the APVMA to use computerised decision-making.

GRDC would see this as the first of other reforms to move away from paper-based systems to electronic. This will allow for the easy transfer of information across Australia and integrate the regulatory system into the digital age and the fast approaching autonomous machine age. A reinstatement of the APVMA PubCRIS app would also be welcomed.

During the implementation of the computer assessments, an auditing of the assessment and a public review of the assessments would improve the trust and integrity of these assessment.

**Proposal 7 – Improve the transparency of voluntary recalls**

GRDC supports the proposed approach to reforms to improve the transparency of voluntary recalls.

**Proposal 8 – Require relevant information to be provided in relation to label approvals and variations**

GRDC supports the proposed approach to reforms on notification of new information

**Proposal 9 – Standards for registered chemical product constituents**

GRDC conditionally supports the proposed approach to reforms on standards for registered products as long as there is sufficient legislative mechanism to withdraw approvals where such changes result in adverse experience reports.

As indicated under proposal 3, there has been instances where what were designated small changes to formulation resulted in change in efficacy. While the proposed changes are deemed low risk certain combined changes across the other constituents could result in decreased efficacy or product stability. If such unintended consequences occur the APVMA needs to have the legislative mechanisms to withdraw the approvals or change the standards.

**Proposal 10 – Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval**

GRDC supports the proposed reform on suspension or cancellation of approval or registration for provision of false or misleading information correcting a current anomaly.

**Proposal 11 – Addressing an inconsistency in label particulars (**

GRDC supports the proposed reform on supply of registered chemical products with unapproved label to clarify label information.

**Proposal 12 – Improving dealings with suspended approvals and registrations**

GRDC supports the proposed reform on variation of approval or registration during suspension. The ability of resurgent and or the APVMA to amend an approval rather than cancel an approval is the preferred option.

**Proposal 13 – Address anomalies in matters that can be prescribed for the statutory criteria**

GRDC supports the proposed reform on safety, efficacy, trade and labelling criteria requiring that the APVMA must have regard to overseas data.

GRDC encourages the utilisation of wider data sets and advocates setting up of agro-ecological co-equivalence areas for crop groups to allow increased use of overseas data.



**Proposal 14 – Simplifying APVMA corporate reporting requirements (*annual operational plans*)**

GRDC conditionally supports the proposed approach to reforms on remove duplication of reporting where the corporate plan is adjusted annually and provides transparency on operational activities of the APVMA.

**Proposal 15 – Align the 2014 legislation review with the overarching review of agvet chemical legislation (*other amendments*)**

GRDC supports the proposed reform

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