Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 Submission 13



## **SUBMISSION**

Response to Australian Government Senate Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014

Date 17<sup>th</sup> April 2014

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PO Box 3517 MANUKA ACT 2603

Committee Secretary Senate Rural and Regional Affairs and Transport Legislation Committee PO Box 6100 Parliament House Canberra ACT 2600 Australia

## Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014

Thank you for the opportunity for Grain Producers Australia to provide a response to the Australian Government Senate inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014. The grains industry represented by Grain Producers Australia (GPA) represents Australia's broadacre, grain, pulse and oilseed producers at the national level. GPA was created to foster a strong, innovative, profitable, globally competitive and environmentally sustainable grains industry in Australia. The objectives of GPA are to establish 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; and facilitate a strategic approach to Research, Development and Extension intended to deliver sound commercial outcomes from industry research.

As stated in a previous GPA submission to Proposed Agricultural & Veterinary Chemicals Legislation Amendments Consultation Paper<sup>1</sup>, GPA supports the proposed key amendments to the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re approval and Re registration) Bill, in particular amendments to Schedule 1 including removal of compulsory re-registration, which has been viewed by industry as an unnecessary administrative process. Changes in the proposed bill allow fast tracking of registrations, contestability of APVMA assessments, improved use of overseas data packages based on agro-ecological co-equivalence and improved agricultural industry access to chemicals for specialty crops and minor uses are also supported.

GPA has been engaged in recent cross industry discussion in relation to increasing market failure of commercial investment in agricultural pesticides and veterinary medicines (Agvet) in Australia. 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. Australia is no longer on the global priority list for pesticide and veterinary medicine commercialization 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. The repeal of the Schedule 1 compulsory re-registration process is a scientifically sound and appropriate decision for the government.

<sup>&</sup>lt;sup>1</sup> Department of Agriculture Proposed Agricultural & Veterinary Chemicals Legislation Amendments Consultation Paper

The proposed removal of Schedule 2 – 47A relating to varying duration—decisions of foreign regulators is supported by GPA. 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 proposed change is an important outcome for technology access for Australian agriculture and productivity impacts, as a large number of chemical 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. As GPA has previously stated, 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. Warnings around the impacts of similar re-registration schemes to Agvet investment in Australia were raised by the Grains Research and Development Corporation in submission to the previous Labor government **Agricultural and Veterinary Chemicals Legislation Amendment (Agvet) Bill 2012.** 

GPA supports the government's decision that APVMA reconsiderations are based on science-based evidence or adverse events for reconsideration of existing chemical actives, not on the basis of time bound compulsory re-registration for no apparent scientific reason. The Australian grains industry and GRDC is not resourced to meet the potential significant cost of increased market failure for regulatory support of generic off-patent chemical actives if this were to occur.

The existing APVMA Chemical Review Program which includes chemical actives in priority 1-4 groups is already in place to deliver the Government policy objective of ensuring safety to human and environmental health and trade. The limited resources of the APVMA should be targeted to assessing new risks based on new scientific knowledge, and investigation of adverse events. It should be recognised that the passing of time and occurrence of any adverse events during this period is a significant determinant of any unidentified risks of older chemistry becoming scientifically evident. It is not a sound strategic scientific approach to spread resources across the entire chemical portfolio, particularly for an increasing number of low risk chemicals. Hazards such as using electrical power points can be easily managed through appropriate risk management, using switches and residual current devices and therefore do not ban its use. Likewise chemical hazards can be very effectively risk managed through appropriate use to deliver high levels of environment, trade and human safety. Policy should continue to focus on worlds best practice risk based management assessment as adopted in North America, rather than the hazard based approach that has been adopted in the European Union that in many cases has failed to recognize that risks can be effectively managed.

The strengths of the Agvet legislation include;

- Science based pre-market risk assessment;
- A targeted chemical review scheme where a potential new risk can be assessed and prompt action taken;
- Obligation of registrants to provide new data where they become aware of new risks (s161);
- An established international framework where the APVMA actively seeks out new information in collaboration with overseas regulators, and where the scientific community or general public can make submissions for review.

## Summary comments

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.

To address the key strategic issue of productivity impacts from declining technology access, GPA recommends that the government urgently address the following;

- 1. Establish a cross industry task force for improved technology access for agricultural production (ITAAP).
- 2. Provide government leadership in the establishment of a cross industry minor use and specialty production initiative (MUSPI), which should be jointly managed by cross industry research and development corporations.
- 3. Consider increased international partnership in co-regulation and look for efficiencies and incentives for Agvet investment in Australia
- 4. Consider future regulatory reforms to underwrite these opportunities and initiatives

GPA is committed to further discussion with the Australian government on the need to deliver transformational change on this issue. There is commitment from GPA to work cross industry and deliver productivity outcomes to agricultural industries and the Australian economy and community.

Yours sincerely

Andrew Weidemann Chairman GPA