

17th August 2016

The Productivity Commission
Regulation of Australian Agriculture
Email: agriculture@pc.gov.au

Regulation of Australian Agriculture, Productivity Commission Draft Report, July 2016

RE: Response to Productivity Commission

Horticulture Innovation Australia Limited (Hort Innovation) welcomes this opportunity to contribute to the Productivity Commissions draft Report on the 'Regulation of Australian Agriculture'. In particular, Hort Innovation would like to provide comment on issues raised in the Draft Report in relation to section 6.2 Access to agricultural and veterinary chemicals.

Hort Innovation is a not-for-profit, grower-owned Research and Development Corporation (RDC) for Australia's \$9 billion horticulture industry.

Hort Innovation's key functions are to:

- provide leadership to, and promote the development of the Australian horticulture sector
- increase the productivity, farm gate profitability and global competitiveness of horticultural industries
- promote the interests of horticultural industries overseas including the export of Australian horticultural products.

Firstly, given the broad diversity of horticultural production in Australia, in terms of location, cultural background of growers, crop types and production systems Hort Innovation believes that the processes involved in chemical regulation should aim to be relatively uncomplicated and consistent while maintaining appropriate standards and safeguards.

From this perspective Hort Innovation believes that the regulatory system should be able to efficiently assess agvet chemicals while ensuring their safety, i.e., provide the level of environmental and consumer protection deemed necessary by the wider community. Hort Innovation therefore appreciates the importance of the issues raised in the draft Report, providing the following comments and offers in principle support to the draft recommendations 6.2 and 6.3.

The time and cost required to achieve chemical registration

The issue of gaining access to new agricultural chemicals has been an ongoing issue in horticulture with the primary impediment being the small size of many horticultural industries and their lack of commercial attractiveness from the perspective of chemical registrants. Fees and the cost of meeting data requirements, no doubt, play a role in registrants determining investment priorities, however, given the application fee and timeframe for a new active ingredient in the USA is USD\$627,568¹ and 24 months,

¹ <https://www.epa.gov/pria-fees/fy-201617-fee-schedule-registration-applications#registration>



compared to Australian fees of ~AUD\$96,135² and a 18 month timeframe, the significance of market size as the overriding determinant driving registrant investment would seem apparent.

Access to agvet chemicals for minor uses

A comparison of approvals in the USA and Australia between the years 2007 and 2012 shows for the majority of new agricultural chemicals, the first registrations in both countries are generally concurrent (see Attachment I). However, there is a marked difference between the numbers of crops, for which approvals are first sought, with the number of crops appearing on US product labels appreciably larger than in Australia. An outcome of which, for minor crops, is that over time the only means of gaining access is via minor use permit applications, which results in approvals for Australian growers occurring some years after their US counterparts.

This highlights the underlying issue that small industry size and lack of, or poor profitability, from a registrant's perspective, deters investment. From that viewpoint Hort Innovation believes that allied with regulatory reform to improve efficiency attention needs, also, to be directed towards identifying potential incentives that would motivate registrants to broaden product labels thereby facilitating access to minor crops. As indicated in the draft Report the Australian Government has provided \$8 million over four years to improve access to minor use chemicals. While Hort Innovation applauds the program this is an initiative currently with an expiry date after which the problem facing minor crops will remain. In order to improve access in the long-term Hort Innovation believes consideration should be given to providing incentives to registrants to include minor crops. This could be done through a mix of options such as expedited reviews, reduced fees, provisional registrations or extensions in data protection, all mechanisms available to regulators in other jurisdictions such as Canada and the USA. The exact framework of incentives and how they might be applied needs to be explored.

Increasing the use of international evidence

Hort Innovation agrees there is scope for the APVMA to increase its use of overseas data and overseas assessments. However, Hort Innovation has some reservations over certain aspects as outlined in the draft Report. Firstly, regarding the proposal that an agvet chemical, registered by two trusted international regulators, could be registered in Australia without further assessment. It is unclear how this would be managed in practice, who would be tasked with determining that use patterns are the same and more importantly that the risks posed were equivalent?

Secondly, it is also unclear whether it would be possible to amend or modify a use based on an overseas decision; given there would be no data/information available locally. If the APVMA needed to access data from an overseas regulator, would this undermine the objective of the approach, as well as potentially raising issues of intellectual property rights where products are marketed by different companies in different jurisdictions?

Finally, the proposal rests on identifying international regulators that undertake assessments with similar outcomes in risk management. It is unclear how these regulators are to be determined and who will have that responsibility? Hort Innovation also expresses a degree of nervousness that the identified regulators would be prescribed in legislation and how this might be applied and amended if necessary. Overly prescriptive legislation could prove counterproductive hindering rather than improving the situation. Hort Innovation also

² <http://apvma.gov.au/node/1088>

believes such an approach could prove problematic should a change occur in the regulatory approach of a nominated international regulator, i.e., were that regulator to move away from a risk-based weight of evidence approach to one in which decisions are driven by a changed policy framework, e.g., to a hazard based approach.

Nevertheless, Hort Innovation believes that opportunities to use international evidence by the APVMA in its assessments should be pursued, though expresses reservations over proposals in which international assessments are adopted without some level of appropriate scrutiny relevant to Australian circumstances.

Inconsistencies across states and territories in control-of-use regimes

As indicated in the draft Report concerns over the inconsistencies in State control-of-use regulations are not new, and believe having a harmonised national control-of-use framework is desirable and would support the Draft Recommendation 6.3. Hort Innovation would therefore welcome an opportunity to engage in any future activities aimed at further progressing this work.

Labelling of agvet chemicals under work health and safety regulations

Hort Innovation understands the aim of GHS labelling is to provide a harmonised system for classification and labelling of chemical hazards. Within that context Hort Innovation recognizes the value of certain GHS elements. However, questions the benefit of its inclusion in agvet chemical labels.

The safe use of pesticides by farmers in Australia is underpinned by the current risk-based system for classifying and labelling of pesticides. This system is well developed and uses internationally accepted risk-assessment processes. In Australia agvet chemical labels are the prime medium of risk communication, in that label directions provide information on the necessary risk mitigation measures required. With the inclusion of GHS hazard based label elements Hort Innovation is concerned that confusion could be an outcome. Hazard statements are generally short but are based on potentially difficult concepts with which many users would not be familiar, e.g., 'harmful to the soil environment' or 'may cause damage to organs'. What is not apparent is whether the hazard identified relates the nature of exposure, i.e., chronic or acute effects. This could result in significant differences in interpretation and action by users, placing the onus on users to undertake their own risk assessment to try and determine risk management measures, disregarding existing label risk minimisation statements.

Yours Faithfully,

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