1. Using overseas decisions as basis for registration

The Australian Government is improving access to agricultural chemicals and veterinary medicines (agvet chemicals) as part of the Agricultural Competitiveness White Paper. Our plan to build a stronger, more prosperous agricultural sector and economy.

This paper seeks your views on one proposed reform to the agvet chemicals system—using overseas decisions as a basis for registration.

It will be used as a basis for discussion at workshops to be held in Canberra, Perth, Brisbane, Sydney and Melbourne from 27 October to 13 November 2015. If you are unable to attend these workshops and would like to provide feedback on the reforms, please email agvetreform@agriculture.gov.au by 30 November 2015.

Problem / Opportunity

Australia's food and fibre production competes for market share in both international and domestic markets. Safe access to appropriate agvet chemicals is essential to maintaining industry competiveness and sustainability in both of these markets.

Stakeholders have advised the department of examples where products that are available to farmers in markets overseas are not available in Australia. Chemical manufacturers tell us that the cost of bringing a product to market in Australia, which relates largely to the burden imposed by the Australian regulatory system, coupled with the relatively small size of the market, means products will not be registered in Australia at the same time as in the overseas markets or, potentially, at all.

This results in Australian producers relying on older, less effective, or less tailored chemistries, where a chemical solution is not available at all. The costs of farm production for Australian chemical users are higher as a result. Limited chemical choice increases the risk of chemical resistance, increases reliance on chemistries developed before modern regulatory scrutiny, and increases the cost of pests and diseases through reduced yield and poorer crop and animal health.

What we have heard

The lack of access to chemicals in Australia that are available overseas was stated as a key factor in the viability of some industries, in particular emerging industries, and as a cause of lower yields for growers of commodity crop and livestock products.

While there was strong support for measures that would improve chemical access in general, farming stakeholders expressed some concern with how Australia's regulatory scheme may be perceived, both domestically and internationally, should this measure be implemented. They felt the rigor of the assessment by the Australian Pesticides and Veterinary Medicines Authority (APVMA) provided a sound base for assuring markets of the quality and safety of Australian produce. An 'easier' registration pathway may be interpreted in international markets as a reduction in the rigor of the Australian decision making process.

Chemical manufacturers expressed similar concerns to those of farmers. The approach requires caution, particularly with respect to its scale and effect on Australia's international regulatory reputation. Chemical manufacturers expressed strong reservations about any approach that would compromise their intellectual property or lead to an increased liability for products or uses they do not support in the Australian market.

All stakeholders clearly stated a need to carefully determine which regulators could be trusted and which could be considered comparable to the APVMA, and the degree to which the Australian circumstance warrants unique assessment. The uniqueness of Australia's fauna and flora, of some Australian environments, and some Australian farming, fishing and forestry practices were highlighted. Some stakeholders were concerned about whether the approach would encourage parallel importation of agvet chemicals and about protecting intellectual property.

There was support for a considered and incremental adoption of this proposal, with initial product types being those where the circumstances of use are identical between countries and where the possibility of environmental exposure is very low. Only after successful operation should the approach be expanded to broadacre or environmentally exposed products.

The proposed reform measure

It may be possible to no longer have APVMA assess products that are registered by trusted comparable regulators overseas where the risks of using the product are the same as in the overseas market. It may also be possible to no longer have APVMA assess new uses of products registered in Australia that are also registered by trusted comparable regulators overseas where the risks of that use are the same as in the overseas market.

While the Australian agvet chemical regulation system is unique, the underlying approach is common to international regulators. Comparable overseas regulators rely on robust objective scientific evidence to make decisions about allowing products to enter their market. Greater reliance on the decisions of these comparable regulators would lower the cost of the APVMA decision making process and so improve safe access to newer, better agvet chemicals for Australian farmers.

The APVMA is finalising its policy on the use of international data, guidelines and standards. The APVMA has indicated it will accept hazard assessments that are unredacted and accompanied by the underpinning data (to allow it to do a 'peer review' and ensure data protection where necessary).

The proposal outlined in this paper, if implemented, would require legislative changes and would therefore provide certainty for applicants about how the APVMA will use international decisions.

Under this proposal, the APVMA would register a product based solely on the decision of two trusted comparable international regulators to register the same product. This would only occur where the risks posed by that product are equivalent between the jurisdictions. Equivalency would mean the overseas product and the Australian product would have the same use pattern (host, pest and application rates), formulation and manufacturer. The international regulators would be prescribed in regulation and reflect those who undertake product specific assessments with similar outcomes in risk management.

While international jurisdictions may have a similar general attitude to risks when registering agvet chemical products, the specifics of their approach may differ. The reliance on decisions from more than one jurisdictions would provide greater certainty in the management of risk.

Recognising the uniqueness of the Australian environment (for example a rainfall significantly lower than other countries and lower ground water levels) and the need to progress in a measured manner; the initial phase would be limited to circumstances where the environmental impact of the chemical is minimal or strictly controlled. The circumstances in which this approach could be utilised would be prescribed in regulation.

We consider this approach could be applicable to:

- companion animal products
- home garden/domestic use products
- products for ornamental plants
- products for use in protected cropping situations (such as greenhouses)
- products for use in intensive enclosed livestock production (such as poultry, pork, or land based aquaculture), and
- new uses of existing products utilising existing approved application methods (for example a product approved for use through boom spray for one pest in a crop may be approved for another pest in the same crop when applied by boom spray).

If implemented, the streamlined process would operate in parallel with the existing process for registration. The choice of registration pathway would be a matter for the company seeking to register the product to decide. It would be possible to register a product using the streamlined process then subsequently decide (perhaps after a trial period) to register the process under the full assessment process.

Should the proposed measure regarding removing trade assessments (Number 4) not be implemented, under this measure these assessments would continue to be required in some circumstances but would be substantially simplified. Adoption of the international Maximum Residue Limit (MRL) as the domestic MRL[1] could potentially address both the criteria for residue safety and to support the assessment of the trade impact of use.

A label that meets the APVMA's labelling criteria would continue to be required.

Requiring prospective registrants to supply information that supports equivalency of product (such as the particulars of the product recorded by the international regulator, including product formulation and sites of manufacture) is expected to ensure that control of intellectual property related to the international product is not compromised. Provisions would be drafted to ensure compliance with international obligations about protecting intellectual property (currently only relevant to the Australia-US Free Trade Agreement). The department expects that the necessary information will likely only be held by the holder of the registration in the international market, and so practically limit the proposal to those companies operating in the markets overseas and in Australia.

By relying solely on international decisions about a product, any change in the international market access would be immediately reflected in Australia. That is, a decision by either of the international regulators to suspend a product registered in Australia via the streamlined method would result in

[1] Where MRLs vary between the jurisdictions relied upon, or with any internationally accepted standard for residues in produce (such as adopted by CODEX Alimentarius) the most stringent would be adopted as the Australian standard.

the immediate domestic suspension of that product. Products registered through the long-form process involving the provision of data for assessment by the APVMA would not be affected. Provisions could be created to allow the supply of information to independently satisfy the APVMA of the relevant matters after a product is registered via this proposal.

Next steps

We have been encouraged by stakeholder input on this measure to date and believe it is a reform that could be delivered in the early stages of the wider reform package.

We will be hosting a series of workshops for all interested stakeholders to attend and provide their views on the proposed reform measures. To attend one of these workshops please fill in a registration form.

If you are unable to attend one of the workshops or would like to provide feedback separately, contact the department via email at agvetreform@agriculture.gov.au.

When providing your feedback you might like to consider addressing the following questions:

- Do you support the proposed reform in its current form or would you like further detail?
- If you don't support it, could the reform be amended to achieve your support? If so how?
- Are there any unintended consequences arising from this reform?
- Does the proposed reform result in new issues for you?

Please provide your feedback by 30 November 2015 so we can consider it before finalising a policy paper outlining a comprehensive reform package. The final policy paper will be released for stakeholder comment in the first quarter of 2016.