



6. Contestable provision of assessment services

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—contestable provision of assessment services. This proposal will be informed by the Australian Pesticides and Veterinary Medicines Authority's (APVMA) trial of third party pre-application assessments.

This paper 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

Reducing APVMA assessment effort and improving the timeliness of registration would improve the efficiency of the regulation process. Currently, chemical companies must use the Australian Pesticides and Veterinary Medicines Authority (APVMA) to assess chemical products before registration. It would be possible to have these assessments completed by accredited professionals against assessment standards set by the APVMA. This could reduce the time taken for APVMA to complete its assessment and place more control over the time taken to register a chemical in the hands of the prospective registrant.

The provision of assessments by accredited and audited third party providers prior to submission of the application to the APVMA may allow chemical companies to better manage their timelines for registration. This would also allow APVMA resources to be redirected to higher chemical risk areas.

The approach used could be similar to that for assessing new construction against the Building Standards Code, where a local council will issue an occupancy certificate on the basis of an assessment of the building work by an accredited private building surveyor or certifier.

What we have heard

There has been cautious support for further exploration of this idea.

There was a general view that, if the proposal was to proceed, a strong accreditation system would be required for third-party assessors. This would have to be accompanied by a strong system of auditing of the assessment reports provided by third-party assessors against the standards written by the APVMA. A strong compliance arrangement would be required to limit the prospect of fraudulently provided assessment reports being submitted to the APVMA.

There is a belief amongst stakeholder more generally that the market could deliver assessments faster than under current arrangements. These time savings would be achieved through contracting

a service provider relationship between the company and the assessor that allows the company to provide information to the assessor as it becomes available. Some chemical manufacturing companies have said that they would be willing to pay more for an assessment if it meant getting a product to market sooner.

Some companies were concerned about how this approach would affect our international standing, though specific details were not provided. Other stakeholders thought improvements to the APVMA's existing processes should be the focus of reform rather than introduction of contestability of assessments.

Stakeholders raised two particular issues that would need to be addressed prior to any arrangement commencing. These were whether assessment reports provided by third party providers would be automatically accepted by the APVMA if they were completed by an accredited provider or whether they would have to be peer reviewed by the APVMA before acceptance. A related question is about how to deal with assessment reports provided to the APVMA that were not of the quality that is required for this important work.

Some stakeholders were concerned about the impact of this measure on the APVMA's capacity and capability to assess those applications for which third party assessment may not be available and to complete chemical reviews. It will be important to implement this measure in a way that manages these risks.

The proposed reform measure

The APVMA is currently implementing a trial of third-party pre-application assessments. During the trial applicants may seek, through a third party provider, an assessment of the proposed product for efficacy and the APVMA will consider that assessment when registering the product. This proposal would support the short term goals of the APVMA and provide the framework for the expansion (as appropriate) of third-party assessments to all assessment areas of APVMA consideration. The APVMA's trial will inform the development of an expanded scheme, should it go ahead.

We agree with concerns expressed by stakeholders regarding the need for rigour in the quality of assessors and believe a legislated accreditation scheme for third-party assessors is essential in any expanded scheme. An established accreditation scheme for assessors in legislation would prescribe the requirements for assessors (for example professional experience, insurance, conflict of interest measures and data handling protocols). The accreditation scheme would be supported by an audit programme, overseen by the APVMA, of received reports to ensure quality and consistency, and a compliance program to ensure the integrity of the third party assessment process.

We also consider that assessment reports provided by accredited assessors must be accepted by the APVMA without further assessment so those who seek assessments by accredited assessors can be certain of the outcome of a registration process and to ensure efficiencies are realised. Assessors would conduct their work against APVMA standards developed in conjunction with the APVMA, Department of the Environment, and Department of Health to ensure consistency in Australian Government approach. The APVMA would continue to be the ultimate decision maker in granting a registration to a chemical product. The existing legislative capacity for the APVMA to act to ensure the safety of the Australian public and environment where new information is identified would be unaffected.

While the necessary underpinning changes to the APVMA's legislation could be made in the early stages of reform implementation, developing accreditation criteria and procedures and finalising the assessment criteria that an application would be assessed against will take some time.

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.