3. Removing efficacy assessments

The Australian Government is improving access to agricultural and veterinary chemicals (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—removing the requirement to have the Australian Pesticides and Veterinary Medicines Authority (APVMA) assess the efficacy of agvet chemical products, other than in relation to the safety of the product.

This reform will make products more accessible and affordable without compromising on safety.

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

Before an agvet chemical product, or a new use of an existing chemical product is registered, the APVMA must be satisfied the chemical will be effective. Applicants provide evidence that satisfies the APVMA that a product will work for its stated purpose, often requiring that studies are conducted in Australia. The generation of this evidence is costly and if costs can't be recovered through sales, the product will not be brought to market. This limits access to new chemicals and so limits the options available to Australian farmers and consumers to meet pest and disease challenges, improve productivity and sustainability or reduce costs.

Agvet chemicals are one of the few tools Australian farmers use where the efficacy of the product is signed off by the government—there is no similar assessment for other farm inputs like machinery or fertiliser technology. International governments rarely require chemical registrants to prove the efficacy of their product, except when product efficacy relates to safety. For instance, a product claiming to address a human health or animal welfare risk, such as a vaccine for the Hendra virus in horses, must establish its efficacy.

The prospect of a producer relying on an ineffective product to meet a pest or disease challenge is limited:

- New chemicals are brought to market overwhelmingly by multinational innovator companies with market incentives to ensure the effectiveness of their products. These companies will not risk their reputation by introducing a new product without testing it thoroughly, so duplicating those tests in Australia may not be necessary. The Australian Government, industry and privately funded research and development bodies routinely assess the worth of new technologies to industry, including new chemical technologies.
- Generic products are assessed on their similarity to the product they are copying, and so will be effective if the innovator product is effective.

- Industry groups and individual producers routinely trial new technologies to address pest and weed challenges for themselves. Industry groups and individuals rely on the experiences of others locally and overseas to inform their own decisions about the value of a new chemical. Farmers talk to their peers. Farmers are also increasingly relying on professional advice like agronomists to make good decisions about new chemicals.
- Australian Consumer Law places an obligation on manufacturers to ensure (consumer) products are of acceptable quality and fit-for-purpose. This law also provides consumers a pathway to address any issues should they arise. Negligence law and contract law also motivates manufacturers to ensure their products are effective and may allow farmers to recover losses from a chemical manufacturer if a product doesn't work for its stated purpose (though this is not an ideal solution).

No longer assessing efficacy would reduce the cost of bringing new chemicals to Australia and prevents duplication of regulatory effort, resulting in improved access to newer and better chemicals.

What we have heard

Stakeholders have varied views on this reform.

Most agvet chemical companies (both large and small) shared the view that the current arrangements required companies to do work above and beyond what they would do to assure themselves a product worked. Many said that the efficacy assessment was a barrier to bringing innovative products to Australia. Feedback suggested that the additional cost of satisfying the APVMA was up to $400,000. This is a cost that would need to be recouped through sales in order for the introduction of a product to be commercially viable.

Innovator companies explained to us that they undertake significant amounts of work to satisfy themselves that a product will work in Australia before bringing it to market here. This work is important to protect their brand and ensure they meet their obligations under Australian Consumer Law, an extremely important consideration for large multinational companies. Based on what we have heard about the work chemical companies will do to protect their global reputations and meet their requirements under consumer law, it appears that the risk of a farm business relying on an ineffective chemical product is low and it may be worth the risk if it encourages new products to enter the market.

Large innovator agvet chemical companies, however, have expressed opposition to removing the assessment of efficacy in granting an agvet product access to the Australian market. These companies are concerned that the removal of an efficacy assessment would encourage the proliferation of 'snake oil' products. These stakeholders are also concerned that removal of the efficacy assessment by the APVMA would push too much burden onto farmers and result in undesirable litigation as farmers pursue manufactures of ineffective products.

Agricultural producers cautiously support pursuing this idea further. Many farming stakeholders explained that access to newer, better products was their primary need and that they could observe the effectiveness of a new product and respond accordingly.

It was made clear to us that farmers want products that work.

Farmers are intelligent and capable business operators, often supported by their industry bodies and well connected in their industry. Some commodity industry bodies told us they, and individual farmers, play a role in trialling new products, testing factors including efficacy, informing growers of the outcomes and advising them on approaches. We were told that new products would not be used in production in some industries until the industry body has completed these trials. This is an approach similar to the support growers get from their industry bodies with other major new farm input decisions such as seed trials etc.

Most agricultural industry stakeholders were very clear that farmers are keen observers of how their farm inputs are performing and would respond swiftly if a chemical product was not working. Most would also share this information with peers in the industry. Stakeholders tell us this word-of-mouth would ensure that the market quickly dealt with the ineffective product, with commercial repercussions for the supplier of the ineffective product.

All stakeholders have highlighted concerns about product quality and the implications of these products not working as expected.

Some producers are concerned that a change to current arrangements would force farmers to use litigation to address product efficacy concerns, and the size and financial position of multi-national companies could overwhelm smaller farmers or farming groups. The potential for resistance challenges to be made worse by farmers increasing use of ineffective product should efficacy assessment be removed was also raised as an issue. Other farm industry participants said the risk of resistance has to be balanced with the improved prospects for new products to address the resistance challenge. They understood that good agricultural practice is, and will remain, the responsibility of the chemical user. Similar points on resistance were raised by government stakeholders.

Stakeholders broadly agree that efficacy assessment should be retained where it is necessary to ensure human safety and animal welfare.

The proposed reform measure

The proposal is to no longer have the APVMA assess the efficacy of a product other than where efficacy is essential to the safety of the product itself. Alternatively, the APVMA could assess efficacy only when an applicant for registration requests it to do so.

We wish to explore four ideas for progressing this proposal:

(a) Amend the Schedule to the *Agricultural and Veterinary Chemical Code Act 1994* (the Agvet Code) to remove all mention of a requirement for a chemical product to establish efficacy (except as it relates to safety considerations).

(b) Amend the Agvet Code to no longer require an efficacy assessment of a chemical product when it is registered, but to allow the APVMA to suspend or cancel the registration of a product if it did not meet the efficacy criteria and it was satisfied there were valid concerns that required investigation.

(c) In concert with (a) or (b) make clear that consumer law does apply to farm users of agvet chemicals. This will ensure that the fitness-for-purpose obligation on manufacturers of agvet chemical products could be enforced by the Australian Competition and Consumer Commission and state fair trading bodies.

(d) Provide that efficacy is only assessed by the APVMA where the applicant chooses for it to be a relevant factor in APVMA consideration. This has the advantage of placing the applicant for the product in control of the regulatory effort they will require. Factors informing an applicant's decision will include the expectations of their customers. If this was implemented, product labels would be required to indicate whether efficacy was assessed by the APVMA.

Next steps

Notwithstanding the mixed views on this measure, we 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.