



7. Streamlining import and export regulation

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— streamlining import and export regulation.

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

Import consents

The Australian Pesticides and Veterinary Medicines Authority's (APVMA) written consent is required to import unapproved active constituents or unregistered agvet chemical products into Australia. The APVMA is not obliged to consider chemical risk when granting a consent to import.

In the majority of circumstances, which may be defined, this process imposes a regulatory burden without a corresponding improvement in chemical safety. No longer requiring an import consent in these defined circumstances would reduce costs and delay to industry and free resources within the APVMA to focus on matters of greater regulatory concern.

Export permits

Exporters of unregistered chemical products are required to hold a permit issued by the APVMA that allows them to possess with intent to supply, or to supply an unapproved active constituent or unregistered chemical. This permit covers the time between chemical manufacture and the chemical's export. The process for issuing these permits is largely administrative as the risk associated with use of these chemicals exists outside of Australia. No supporting data addressing safety criteria is required by the APVMA.

In the majority of circumstances, which may be defined, this process imposes a regulatory burden with little or no improvement in the safety of chemical use. No longer requiring a permit for export in these defined circumstances would reduce costs to industry and allow the APVMA to focus on matters of greater regulatory concern.

Export certificates

Some countries require imported agvet chemical products to be accompanied by an export certificate provided by the exporting country's government. The APVMA has provided these certificates to support the export of both registered and unregistered products, but has recently revised its approach to no longer issue the permits for unregistered products.

It is appropriate for the APVMA to provide export certificates about registered products, where matters about those products are within its knowledge and competence. The APVMA's past practice of providing certificates for unregistered chemical products, where it has very little knowledge about the product, is a risk to the APVMA's reputation as a competent and trustworthy regulator. This task is not related to the APVMA's principal responsibility of assessment and control of the supply of safe chemicals in Australia, but is related to the APVMA's secondary responsibility for domestic agvet chemicals manufacturing. Other avenues exist for exporters of unregistered chemical products to seek government certification, including schemes administered by chambers of commerce on behalf of the Australian Government Department of Foreign Affairs and Trade.

Formally limiting the APVMA's role in export certification will allow the APVMA to focus on matters of greater regulatory concern.

What we have heard

Stakeholders generally reflected that the proposed changes are largely procedural or administrative and are expected to deliver a modest improvement in efficiency. Most discussions have supported the removal of burdensome administrative processes that offer limited improvements in the management of chemical risk.

The concern heard most often related to the potential for changes in access to international markets for agvet chemicals (predominantly veterinary medicines) manufactured in Australia. Another concern is about Australia's ability to meet its responsibilities under international conventions, though the specifics of this concern were not made clear in our discussions. The department has established that these reforms would not affect Australia's ability to meet its obligations with respect to these conventions.

Conversations to date have helped us to understand the requirements of some international destinations for Australian-made products and the role the APVMA plays in supporting access to these markets for Australian chemical manufactures.

Many stakeholders have highlighted the importance of maintaining or improving perceptions of our regulatory system overseas.

The proposed reform measure

We understand how important Australia's reputation for competent regulation is in supporting access to markets for Australian products and we will continue to consider reputational issues as we undertake this reform agenda.

We will work with stakeholders, including trade officials in the department and other Australian Government agencies, to understand the risks posed by the reforms. We will also ensure any changes can be properly explained to trading partners to give them confidence in the continued quality of our regulatory system.

These reforms will not lesson the government's ability to meet its obligations under international agreements. These obligations are met through processes that are the responsibility of the department rather than the APVMA.

Import Consents

It is proposed that import consents would no longer be required in those situations where the generation of a consent does not improve management of chemical risk or where that risk is adequately managed by others. This would apply to unregistered products:

- (a) imported for use by, or under the direction of, a veterinary surgeon
- (b) that are the subject of a current APVMA permit, or
- (c) imported up to 28 days prior to the expected date of an APVMA decision on an application to register that product.

In the first two situations [(a) and (b)], the risks of using unregistered products are assessed and mitigated by the professional expertise of a veterinarian or the process for issuing and enforcing compliance with APVMA permits.

Manufacturers and suppliers put effort into ensuring new imported product does not arrive prior to its registration. After registration, the product is shipped by the exporter to the docks and then to stores and farms. For (c), reducing the lag time between a registration decision is made and when supply may start improves the access of farmers to new chemical products. Reducing lag time also maximises the period of exclusive market access given to products registered with protected information.

Providing an importation window prior to registration will remove the costs of an import consent and allow newer, better chemicals to come on to the market as soon as possible.

The APVMA enforcement of compliance with the existing prohibition on supply of unregistered chemical products would continue to manage any risks posed by products prior to registration or in the event registration is not granted. This prohibition operates alongside state and territory laws controlling the use of unregistered chemical products.

Implementation: This change could be achieved by amending section 69B of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* to allow for uncertified imports in circumstances described in the regulations. Regulations for section 69B would then be made describing the three circumstances (a) to (c).

Export Permits

It is proposed that a person be exempt from requiring an APVMA issue permit to supply, or possess with intent to supply an unapproved active constituent or unregistered chemical product outside Australia. The risks of an exported chemical product are already managed through other regulatory schemes including dangerous goods, transport, workplace health and safety or biosecurity regulators.

Implementation: There are several options for legislation implementing this idea. Amendments could be made to the relevant provisions in Part 4 of the Schedule to the *Agricultural and Veterinary Chemical Code Act 1994* to possession or supply of products only for the purposes of export without the need for an export permit. Or regulations could be made describing the circumstances, like possession or supply for export, under which it would not be an offence to possess or supply an unregistered chemical product. Or regulations may be able to be made exempting products for export from the relevant provisions of the Agvet Code.

Export Certificates

The department originally explored the proposal that the APVMA completely cease all export certification. As a consequence of views from stakeholders we have altered our proposal to retain the APVMA's responsibility for export certification of registered products only.

The revised approach recognises the efficiency of having the APVMA provide export certification services about products it has responsibility to assess and register. The APVMA assessment of a registered product allows confirmation of a products availability in Australia and particulars. This approach recognises that some importing countries rely on the APVMA's expertise and knowledge in risk assessment and international reputation to inform their own decision.

The APVMA may have only limited knowledge of an unregistered chemical product. Issuing export certificates for unregistered products may risk damaging the international reputation of, and confidence in the APVMA.

The Australian Government would continue to play a role in supporting international trade in Australian manufactured goods, including of unregistered chemical products. This is the specific remit and expertise of agencies promoting Australia's trade—such as the Departments of Foreign Affairs and Trade and Agriculture and Water Resources—as is the case for other Australian commodities and manufactured products.

Implementation: This change could be achieved by amending section 69D of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* to allow certificates to be issued by the APVMA only for registered chemical products. The certificate could provide any information about the registered product, including about manufacturing of products (for example, information about compliance with Good Manufacturing Practice for veterinary chemical products).

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.