



INFORMATION SHEET

Australian Pesticides & Veterinary Medicines Authority

Permits Scheme

The law requires that all agricultural and veterinary chemical products sold in Australia be registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

In most States, registered products must only be used for those approved purposes that are specified on the label. In practice, situations often arise where chemicals are needed for a use not specified on the label.

The APVMA has a Permits Scheme in place that allows for the legal use of chemicals in ways different to the uses set out on the product label. These are often called 'off-label' permits. In certain circumstances, the limited use of an unregistered chemical may also be allowed by Permit.

Obtaining a permit requires the applicant to satisfy the same criteria as for registration. Essentially these are the demonstration that the chemical product is safe for people and the environment, won't affect our international trade through residue problems and is effective.

However as the extent of the chemical's use may be quite small and the related risks much lower, the supporting data requirements and evaluation processes may be simpler.

Types of Permits

Permits fall into three groups.

- minor use permits which apply to situations usually involving new crops or low acreage crops or small portions of high acreage crops;
- emergency use permits for situations such as outbreaks of exotic diseases or pests; and
- trial permits which allow for chemical products to be used in research trials of varying size for scientific purposes, such as generating the data necessary to register the product.

More on Minor Use Permits

Minor use situations typically concern those uses that have not been included on the registered label of a chemical product because the registrant judged that it was not economical to do so.

There can be significant cost involved in generating the scientific data necessary to support registration of an agricultural or veterinary chemical product.

Naturally enough the product registrant will only pay to obtain data that supports those uses likely to be profitable. In effect, this means chemical uses for which there is significant demand.

However there can be many situations where a chemical product is necessary but the overall market demand is small or unknown and therefore not of economic interest to the registrant.

These can include:

- use on a speciality crop or animal grown by only a few producers on a small scale;
- infrequent use or where use is restricted to a small percentage of a major crop or for the control of a minor disease;
- unusual seasonal conditions requiring a changed method or rate of application; or
- emergence of a new crop.

The APVMA Permits Scheme provides rural producers with legal access to chemical products necessary to the success of their businesses. Because of the high scientific standards followed in the decision process, permit holders can be confident that the chemical they use is likely to do the job safely and effectively without resulting in residue problems that could affect the saleability of their produce.

Minor use permit approvals are generally restricted to currently registered products for which the relevant scientific data has been assessed. Residues in treated crops need to be assessed to establish appropriate Maximum Residue Limits (MRLs) and withholding periods as part of the permit approval for minor use.

APVMA Permit Scheme continued...

The MRL is the highest concentration of chemical residue that is legally permitted in a primary product. It is based on the residue level that might be expected in a product if the pesticide or other chemical is used according to the directions on the label. MRLs are set as low as possible while still permitting the chemical to work effectively.

There are a number of options possible to reduce the burden of establishing MRLs associated with minor use permits – such as data extrapolations and temporary MRLs. The APVMA can provide detailed advice on what it requires to approve an MRL.

More on Emergency Permits

A permit application for emergency use of a chemical is evaluated quickly to respond to the problem situation. While these applications cannot be subject to the same requirements or processing procedures as a normal minor use permit application, additional conditions or controls may be applied during the emergency.

In all emergency cases however the APVMA will work through the relevant State or Territory government authorities to verify whether or not the application concerns a genuine 'emergency'.

'Emergency' in this case refers to an urgent need to control a pest or disease that has just become evident. Economic pressure or urgency is not an emergency.

Applying for a Permit

Any suitable person or organisation can apply for a permit. In cases where the majority of an industry requires the off-label use of a registered chemical, the peak grower organisation would be the most suitable permit holder.

In applying for a permit it is necessary to submit the completed application form to the APVMA. Detailed information is required in a number of specific areas to do with the chemical product and its proposed application such as

- what products are to be used;
- how the products are to be used;
- where they are to be used; and
- who will use the products

The application form and more detailed information on using the Permits Scheme can be found on the APVMA web site or obtained by phoning the APVMA.

Costs and Time Taken

Permit assessment is done on a fee for service basis. The fees that are charged vary according to the amount of technical assessment and consultation required.

There is no fee to obtain a permit for emergency use or for an application received from primary producers or government agencies.

The time taken to complete the assessment and issue the permit varies with the complexity of the situation. In the majority of cases for minor use

You can now search for existing permits online
www.apvma.gov.au/permits/permits.shtml

Contacting the APVMA

Want More Information?

If you would like to know more about the APVMA or any of its services please contact us.

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