



INFORMATION SHEET

Australian Pesticides & Veterinary Medicines Authority

The Registration Process

Before an agricultural and veterinary chemical product can be legally supplied, sold, or used in Australia it must be registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

For farmers, food producers, the chemical industry and the general public, registration means that the product is safe and will work when used according to the label.

The Registration Process

Each chemical product submitted to the APVMA for registration undergoes rigorous scientific assessment before it can be approved. In evaluating products the APVMA takes full account of the nature of the product, the scientific quality of the data and comments from consultation with manufacturers, Commonwealth advisory agencies, State and Territory departments and other stakeholders, including the public.

Information Required to Register a Product

When an application for registration is submitted to the APVMA, the product registrant must supply enough information to establish that the product meets four criteria. They are:

- human and animal health and safety;
- efficacy - that the product works;
- environmental safety and
- that it will not affect international trade.

Evaluation

Specialist staff in the APVMA examine the product and its ingredients. The chemistry of the product, how it was manufactured and the residues it leaves behind after its use are also assessed. In addition, where necessary, the APVMA will seek specialist advice from a number of Commonwealth agencies and where appropriate consults with the States and Territories (Departments of Agriculture) and other specialist external organisations.

These include:

- The Therapeutic Goods Administration (TGA);
- Environment Australia (EA);
- National Occupational Health and Safety Commission (NOHSC);
- The Australia New Zealand Food Authority (ANZFA);
- The Office of the Gene Technology Regulator (OGTR);
- The Expert Advisory Group on Antimicrobial Resistance (EAGAR); and
- The Australian Quarantine and Inspection Service (AQIS).

Label Directions

As part of the assessment the APVMA also evaluates the product label. The APVMA examines how the chemical will be used, the application rate, method of application and concentration levels to ensure the product's maximum efficacy. Preparation, storage and first aid instructions are also carefully assessed to safeguard human and environmental health and safety.

Public Consultation

To inform the public that a new product is being considered for registration, the APVMA places a notice in the APVMA's Agricultural and Veterinary Chemicals Gazette, (available from the APVMA website) and sends a summary to interested members of the public and relevant industry bodies seeking comment. All comments are considered before the final decision on whether to register the product is made.

Registration Timeframe

The registration of a product can take between 3 and 15 months. This allows time for screening of an application, hands-on evaluation of the data submitted, specialist consultation (where necessary) and public consultation. Therefore the time required to register a product varies, and is dependent on the level of evaluation and assessment required.

The Registration Process continued...

Product Review

Chemicals are not registered forever. The APVMA has in place a chemical review program that reconsiders whether older registered agricultural and veterinary chemicals meet today's standards for safety and efficacy. The program also looks at newer chemicals where there are concerns for public health and safety.

Possible outcomes of a review include: continued registration, changes to how the chemical can be used, suspension of chemical use or the product being withdrawn from the market.

The APVMA Permit Scheme

The APVMA has a Permits Scheme in place that allows for the legal use of chemicals in ways that are different to the uses set out on the product label or, in certain circumstances, the limited use of an unregistered chemical.

Obtaining a permit requires the applicant to satisfy the same criteria as for registration. 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.

Chemicals the APVMA Registers

The APVMA assesses and registers agricultural and veterinary chemical products.

- Agricultural chemicals include herbicides, insecticides, fungicides and some pest traps and barriers for pest control.
- Veterinary chemicals include, vaccines, antibiotics, anaesthetics, para and ectoparasiticides and some vitamins and minerals.

In addition any major variation to the ingredients or use patterns of a registered product must also be assessed and approved by the APVMA.

The APVMA's role is that of an industry regulator. It is not involved in identifying opportunities in the marketplace and promoting registration of a product to meet this purpose. It is up to chemical companies and individuals to identify a need and develop a suitable product. Alternatively, farmer associations may identify a market for a new product and convince chemical companies to develop and register a product that meets this identified need.

Biological and Natural Products

Biological or natural products are sometimes used for the treatment or protection from pests and diseases.

In cases where a product lays claim to controlling a particular condition or having beneficial effects, then registration may be required. To find out if a biological or natural product does require registration contact the Registration Client Services of the APVMA.

The Benefits of Using Registered Products

By purchasing registered chemical products, you know:

- they have been assessed as suitable for use under Australian conditions;
- you are complying with the law; and
- when used according to the label, they will not have any negative effects on you, your family, your crops and animals or the environment.

The Label, the Key

By following the label on the products registered by the APVMA you know that you are:

- using the right product the right way;
- minimising waste and cost; and
- getting the right advice on safety, preparation, application and storage.

Contacting the APVMA

Want more information?

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

Postal address:

PO Box E240
KINGSTON ACT 2604

Phone:

02 6272 5158

Fax:

02 6272 4753

Website:

www.apvma.gov.au



Australian Pesticides &
Veterinary Medicines Authority