



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.

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, anthelmintics, 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 a market 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 request 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 claims to control a particular condition or have beneficial effects, registration is required. To find out if a biological or natural product does require registration contact the Application Management & Enquires section of the APVMA.

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 criteria of:

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

Screening

Each application is given an initial check (known as "screening") to determine that it contains the required supporting data and information. Applicants are advised of any deficiencies.

Evaluation

Specialist staff in the APVMA examine the product and its ingredients. The APVMA also assesses the chemistry of the product, how it was manufactured and any residues it leaves behind after its use. The APVMA commonly seeks specialist advice from a number of Commonwealth agencies and where appropriate consults with the states and territory Departments of Agriculture and other specialist external organisations.

These include:

- The Therapeutic Goods Administration (TGA);
- Department of the Environment, Water, Heritage and the Arts (DEWHA);
- Foods Standard Australia New Zealand (FSANZ);
- The Office of the Gene Technology Regulator (OGTR);
- The National Health & Medical Research Council (NHMRC); and
- The Australian Quarantine and Inspection Service (AQIS).

Label Directions

As part of the assessment the APVMA also approves 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 with a new active constituent 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.

Where a change to a label may have impact on trade the APVMA seeks advice on this aspect from relevant industry bodies and the public.

Registration Timeframe

Assessments of a product application can take between 3 and 15 months. This allows time for screening of an application, 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.

Product Review

Chemicals are not registered forever. The APVMA has 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 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.

To obtain a permit, the applicant needs to satisfy the same criteria as for registration. However, because 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.

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

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.

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