

Veterinary Medicines and the ACVM Act

502 ACVM 03/05

THE AGRICULTURAL COMPOUNDS AND VETERINARY MEDICINES (ACVM) ACT 1997

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, which commenced on 2 July 2001, is the primary legislative tool to regulate veterinary medicines and their use in agricultural and livestock production in New Zealand. The ACVM Act is administered by the ACVM Group of the New Zealand Food Safety Authority (NZFSA) (for more details, see our fact sheet entitled *The ACVM Group*).

Purpose of the Act

The purpose of the ACVM Act is to:

- a. prevent or manage specific risks associated with the use of agricultural compounds –
 - risks to trade in primary produce
 - risks to animal welfare
 - risks to agricultural security;
- b. ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards;
- c. ensure the provision of sufficient consumer information about agricultural compounds.

What is an 'agricultural compound'?

The ACVM Act defines an agricultural compound as:

any substance or mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land or water on or in which the plants and animals are managed, for the purposes of –

- a. *Managing pests, including vertebrate pests; or*
- b. *Maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or*
- c. *Fulfilling special nutritional requirements; or*
- d. *The manipulation, capture, or immobilisation of animals; or*
- e. *Diagnosing the condition of animals; or*
- f. *Preventing or treating conditions of animals; or*
- g. *Enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or*
- h. *Marking animals*

and includes any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest pest control or disinfestation of raw primary produce, and any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2).

Veterinary medicines

Agricultural compounds have been divided into three groups for regulatory purposes, and veterinary medicines make up one of these groups.

A veterinary medicine is defined by the ACVM Act as being “*any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal*”. This includes all animal feeds. Items that are inert and do not diffuse into animals are not covered by the Act, e.g. horse shoes.

Regulatory control

For veterinary medicines, regulatory control is applied only in regard to compounds that are to be used on animals for any of the purposes listed in the definition of an agricultural compound and only to manage the risks specified in the purpose of the Act.

Control mechanisms

The ACVM Act provides two main mechanisms for regulating agricultural compounds:

- registration
- exemption from registration.

Any product that is a veterinary medicine, but not exempted from registration, must be registered. Virtually all registrations will have conditions that govern any or all of the following:

- manufacture
- sale
- use
- importation.

Products without restrictions on sale or purchase are known as over-the-counter (OTC) products. Other products that may be sold and used only under a veterinary prescription or authorisation are known as prescription animal remedy veterinary medicines (PARs).

Use only products that are registered or exempt from registration. If in doubt check on the ACVM Group's website or with the ACVM Group.

Always comply with the conditions of registration or conditions of exemption from registration.

Whenever relevant, use the product according to the label instructions and abide by the specified withholding period.

The ACVM Group maintains a public register on its website (www.nzfsa.govt.nz/acvm) of all registered products. The register contains basic information on the product and a cross reference to a scanned version of the label content. The list is searchable by active ingredient, product type, trade name etc.

Trade name products

Because the levels of relevant risks are closely associated with particular formulations and use, the provisions of the ACVM Act are focused on the regulatory control of 'trade name products'. A trade name product is:

an agricultural compound (or veterinary medicine) identified and packaged under a trade name for a specified use or uses.

Trade name products are exempted from registration by groups prescribed in the *ACVM Regulations 2001*, e.g. first aid products or lubricants. Products that are exempted from registration do not have specific conditions, but must be used in accordance with the conditions specified in the Regulations.

Codes of practice

The ACVM Act allows for the approval of codes of practice for importing, selling, or using any agricultural compound. These codes provide guidance to help people comply with conditions of registration.

Managing risks under the ACVM Act

Veterinary medicines are assessed for efficacy where claims are made to treat or prevent a disease that causes pain or distress in animals. Where product inefficacy will not lead to compromised animal welfare, the ACVM Group will not conduct an efficacy assessment during the registration process. This applies to most zotechnical products where claims are limited to the enhancement of animal productivity.

Veterinary medicines are assessed to ensure that target animal safety risk thresholds are not exceeded. This means that the use of the veterinary medicine must not result in unacceptable pain or distress in the target animal.

In addition, to ensure there are no risks to trade in primary produce or breaches of the domestic food residue standards, veterinary medicines containing active ingredients that require a maximum residue limit (MRL) will undergo a residue assessment during the registration process. A withholding period can then be set; it represents the time at which edible products (meat, milk, honey, eggs) contain residue levels below the MRL and are therefore considered eligible for human consumption. (See our fact sheet entitled *Maximum Residue Limits/MRLs*.)

In regulating agricultural compound trade name products, the ACVM Group imposes labelling obligations to ensure that the parties using the products have sufficient information to use the products appropriately and safely, and that the products are truthfully identified.

REMEMBER

Not taking due care to comply with the conditions of registration on agricultural compounds or veterinary medicines could be an offence under the ACVM Act. In addition, your actions could result in offences under the Hazardous Substances and New Organisms Act 1996, Animal Products Act 1999, Food Act 1981 and Animal Welfare Act 1999.

Obligations

Under the ACVM Act, products are assessed and registered for a recommended use, and conditions are placed on the registration of products to manage or reduce risks. These conditions may be either generic or product specific, potentially affecting importers, registrants, distributors and users. Specific conditions are applied to manage risks not managed by generic conditions. Basically, every manufacturer, retailer and user must comply with the conditions imposed on a product's registration or exemption from registration.

Any condition that specifies an obligation on users or a limitation on the use of a product will be stated explicitly on the label, which includes written material provided with the product.

Off-label use

Sometimes there is a need to use a product in a manner or on animals that are not specified in the registration and label information, i.e. off-label use. Any use that has not been specifically approved by the ACVM Group is considered to be an off-label use.

The conditions on a particular product may provide for off-label use if certain requirements are met. For OTC products, users must seek veterinary advice prior to off-label use. For PARs, veterinarians may use registered veterinary medicines off-label only when acting in accordance with an applicable code of practice approved under section 28 of the ACVM Act. Currently, the code in force is *The New Zealand Veterinary Association Code of Practice for the Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians*.

This opportunity to use a product off-label will not be noted on the label. Users should refer to the ACVM Group public register to see what conditions have been imposed. If you need to use a product in an off-label manner, check the conditions of registration to determine if off-label use is allowed and, if it is, whether it is limited in any way.

An important issue to remember is that some of New Zealand's trading partners have banned the use of certain substances in food-producing animals. The ACVM Group holds a list of these substances and, if unsure of the status of the substance to be used, users must check with the ACVM Group prior to any off-label use.

Further changes

The regulation of veterinary medicines changes from time to time. Keep up to date by:

- putting your name on the contact list to receive our free newsletter *AgVetLink*
- checking the website (www.nzfsa.govt.nz/acvm).

Contact the ACVM Group if you need clarification on any matter. Comments on discussion documents or any other aspect are always welcome.

For more information visit the ACVM Group website (www.nzfsa.govt.nz/acvm) or contact the ACVM Group directly:

ACVM Group
New Zealand Food Safety Authority
P O Box 2835, WELLINGTON
Phone: 04 463 2550, fax: 04 463 2566

Disclaimer: This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.