

The ACVM Group

500 ACVM 03/05

THE NEW ZEALAND FOOD SAFETY AUTHORITY

The New Zealand Food Safety Authority (NZFSA) was created in 2002 from the sections of the Ministry of Agriculture and Forestry responsible for the regulatory control of primary produce and the section of the Ministry of Health responsible for food safety. NZFSA's job is to:

- regulate the safety of the domestic food supply;
- regulate the safety and certification of export primary produce and food;
- establish acceptable levels of food safety, carrying out food safety risk analyses and developing food safety standards.

It also took on responsibility for the safety and welfare of animals in regard to the use of agricultural compounds.

NZFSA is part of the Ministry of Agriculture and Forestry for administrative purposes, but the Authority reports directly to the Minister for Food Safety. Its statutory mandate is based on provisions and Regulations of the:

- Animal Products Act 1999
- Agricultural Compounds and Veterinary Medicines Act 1997
- Food Act 1981
- Wine Makers Act 1981.

The ACVM Group

The Agricultural Compounds and Veterinary Medicines (ACVM) Group is the part of NZFSA that administers the ACVM Act (see box at right). It has primary responsibility for the regulatory control of agricultural compounds (plant compounds, veterinary medicines and vertebrate toxic agents).

Although it is part of NZFSA, the ACVM Group's mandate is broader than food safety. In addition, the ACVM Group is concerned with:

- the welfare of animals treated with or exposed to agricultural compounds;
- possible residues in non-food primary produce; and
- the impact of agricultural compounds on the eradication, prevention and control of pests and unwanted organisms.

Regulation

The ACVM Group is responsible for approving veterinary medicines, plant compounds and vertebrate toxic agents. In regulating such products, the Group places conditions on the importation, manufacture, sale and use of the products and on any person involved in these activities.

The main regulatory tools used are **registration** and **exemption from registration**. Any product that is an agricultural compound must be registered unless it is exempted (see below). The ACVM Group maintains a public register of all registered products on its website (www.nzfsa.govt.nz/acvm).

Trade name products (agricultural compounds, veterinary medicines or vertebrate toxic agents) identified and packaged under a trade name for a specified use or uses are exempted from registration by groups prescribed in the *ACVM Regulations 2001*, e.g. first aid products, 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. (See fact sheets entitled *Plant Compounds and the ACVM Act* and *Veterinary Medicines and the ACVM Act*.) The list of exempted products is also available on the website.

GRAS registers

Many common substances known to present negligible hazards to human or animal health or the environment are used in agricultural compound trade name products. NZFSA considers that repeated safety assessment of such substances when they are incorporated into new trade name products is not necessary. The ACVM Group has adopted a mechanism used in North America and Europe to provide for substances to be assessed by experts, considered by the public and placed on public registers if they are proven to be generally recognised as safe (GRAS) **for the purposes of the ACVM Act**. The criteria for inclusion on GRAS registers are conservative so that substances are classified as GRAS only where they have a proven history of safety when used appropriately.

Standards setting process

The ACVM Group sets registration and regulatory standards and guidelines:

The ACVM Act

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 is one of the outcomes of a wide reform of New Zealand's agricultural legislation begun by Government in the late 1980s. The ACVM Act replaced the Animal Remedies Act 1967, Pesticides Act 1979, Fertilisers Act 1960 and Stock Foods Act 1946 on 2 July 2001.

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.

The ACVM Act is primarily responsive to standards and outcomes set under the other legislation mentioned at left. Agricultural compounds are assessed and controlled under the ACVM Act to ensure that the outcomes and standards set under legislation or by international agreements are not compromised. The Act does not cover risks to human health or the environment, which are covered by the Hazardous Substances and New Organisms (HSNO) Act 1996.

- to make the registration process more predictable for both applicants and the ACVM Group
- to guide people in complying with conditions of registration/exemption.

Registration standards define minimum requirements for designing, conducting, monitoring and reporting laboratory, field and clinical studies to enable the ACVM Group to assess an application to register a trade name product or to vary the conditions on a registered trade name product. Standards, which provide applicants with the chemistry and manufacturing requirements for data packages, are generally based on internationally accepted best practices. These standards (or their equivalent) are mandatory, and deviations require a specific information waiver, based on reasoned technical argument.

Regulatory standards define expectations for complying with conditions of registration/exemption, e.g. *ACVM Standard for Vertebrate Toxic Agents*. All of the standards and guidelines are available on the website.

Consultation

The ACVM Group receives advice on the development of operational policies and procedures that provide the framework for decision making. One of the key parts of the development process is input from groups such as the Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC) and the Industry Liaison Group (ILG). See our website (www.nzfsa.govt.nz/acvm) for more information about these groups.

Another key component of the development of the decision making framework is the process of consultation. The public is informed about policies, issues, etc. through the website and the ACVM Group's free newsletter *AgVetLink*. Comments and suggestions are always welcome.

Setting MRLs

The ACVM Group has the responsibility for setting maximum residue limits (MRLs) under the Food Act (see our fact sheet entitled *Maximum Residue Limits/MRLs*). These are promulgated in the New Zealand Maximum Residues of Agricultural Compounds Standard. The NZFSA Food Residues Co-ordination Group (with members from most sections of NZFSA) provides input on residues for all NZFSA-administered legislation, including the Animal Products Act. Public consultation is also an important part of the MRL setting process.

Prescription medicines

The ACVM Group consults with the Ministry of Health prior to registering agricultural compounds that are prescription medicines or related substances, e.g. there is ongoing consultation regarding the potential for antibiotic resistance affecting humans and conditions needed to manage this.

Toxicology risks

Toxicology risks of a substance to humans and the environment are now managed by the Environmental Risk Management Authority (ERMA NZ), which administers the Hazardous Substances and New Organisms (HSNO) Act 1996. The ACVM Group maintains a close liaison with ERMA NZ regarding applications for registration of agricultural compounds. Registration under the ACVM Act requires prior ERMA NZ approval for any hazardous substance or new organism.

Consumer information

The ACVM Act requires the supply of product information to consumers. In regulating agricultural compound products, the ACVM Group imposes labelling obligations to ensure that people using the products have sufficient information to use products appropriately and safely, and that the products

are truthfully identified. Under the consumer information provisions of the Act, the ACVM Group can ensure that requirements of ERMA NZ and the Ministry of Health in terms of advice on safe storage, distribution, use and disposal are part of the approved label content when a product is registered.

Compliance

Compliance is a significant part of the ACVM Group's responsibility. The purpose of compliance activities is to ensure that:

- agricultural compounds conform to the regulatory conditions provided for in legislation
- people comply with the conditions of registration.

Compliance activities under the ACVM Act provide assurance to the public of New Zealand and/or to the competent authorities of the countries importing New Zealand primary produce that the use of agricultural compound products will not:

- cause any disruption of the export trade in New Zealand primary produce;
- result in serious illness or distress in any animals;
- introduce any unwanted organism into New Zealand or hinder any unwanted organism or pest control programmes;
- reduce national productivity of agriculture in New Zealand; or
- cause unacceptable residues in domestic food products.

Harmonisation

The ACVM Group is closely involved in a number of international harmonisation activities:

- VICH is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. Members are the European Union, the United States of America and Japan, with Australia and New Zealand as active observers (working under the ANZ VICH umbrella).
- On the plant compound side, New Zealand is a member of the OECD, the Organisation for Economic Cooperation and Development, which provides guidance for industry data submissions and the format for regulatory assessments.
- The Codex Alimentarius provides for harmonisation of maximum residue limits for agricultural compounds and veterinary medicines in trade produce. Member countries set these limits by consensus.
- Harmonisation is particularly valuable between Australia and New Zealand and, to that end, the Australia New Zealand Registration Management Committee has been established and is looking at the harmonisation of labelling requirements. New Zealand also is an observer of the Australian Registration Liaison Committee, which deals with compliance issues, and has observer status on the Australian Product Safety and Integrity Committee, which deals with policy development related to agricultural or veterinary chemicals.

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

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