

ISBN 0-478-07821-8

58 ACVM 09/05

New Zealand Food Safety Authority
Post Office Box 2835
Wellington, New Zealand



**ACVM
STANDARD FOR
THE FERTILISER GROUP OF
AGRICULTURAL COMPOUNDS**

This document may be altered at any time. It was current as at the date in the footer of each page of the document. It is recommended that anyone intending to use this document should contact the ACVM Group of NZFSA or check its website (<http://www.nzfsa.govt.nz/acvm/>) to confirm that it is the current version.

Endorsement:

Date:

CONTENTS

1 INTRODUCTION

- 1.1 Scope
- 1.2 Definitions specific to this standard
- 1.3 Subgroups of fertilisers
- 1.4 Regulatory control of substances or products in the fertiliser group offered for sale
- 1.5 Regulatory control of substances or products in the fertiliser group not offered for sale
- 1.6 References

2 REQUIREMENTS FOR FERTILISERS AND FERTILISER ADDITIVES

- 2.1 General requirements for manufacture
- 2.2 Specific requirements for manufacture
- 2.3 Importation
- 2.4 Trade
- 2.5 Use

3 REQUIREMENTS FOR SOIL CONDITIONERS

- 3.1 General requirements
- 3.2 Manufacture, importation, trade and use

4 REQUIREMENTS FOR RAW AND COMPOSTED ORGANIC WASTES

GLOSSARY OF ACVM TERMS

ACVM STANDARD FOR THE FERTILISER GROUP OF AGRICULTURAL COMPOUNDS

1 INTRODUCTION

1.1 Scope

This standard covers the requirements for the fertiliser group of agricultural compounds that are regulated under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. The group is complex, ranging from bulk inorganic fertilisers, organic and augmented organic fertilisers, trace element supplements and soil conditioners, and includes expectations in regard to raw and composted organic wastes.

The standard provides the requirements based on subgroups of similar kinds of substances and products based on the intended action of the products. The relevant subgroups are explained in section 1.3.

1.2 Definitions specific to this standard (for general ACVM terms see the Glossary)

Fertiliser

- (a) a substance or biological compound, or mix of substances or biological compounds that is described as, or held out to be for, or suitable for, sustaining or increasing the growth, productivity, or quality of plants or, indirectly, animals through the application to plants or soil of:
 - (i) nitrogen, phosphorus, potassium, sulphur, magnesium, calcium, chlorine, and sodium as major nutrients; or
 - (ii) manganese, iron, zinc, copper, boron, cobalt, molybdenum, iodine, and selenium as minor nutrients; or
 - (iii) fertiliser additives; and
- (b) includes non-nutrient attributes of the materials used in fertiliser; but
- (c) does not include substances that are plant growth regulators that modify the physiological functions of plants.

Fertiliser additive

- (a) a non-nutrient substance added to a fertiliser, or applied to land by itself, that—
 - (i) improves the supply and uptake of nutrients; or
 - (ii) increases the biological activity of soil; or
 - (iii) modifies the physical characteristics of a fertiliser to make it more fit for its purpose; but

(b) does not include substances that are plant growth regulators that modify the physiological functions of plants

Organic wastes

Any material of animal or plant origin that has not been subjected to a process that assures the content and safety of the material. It includes all unprocessed animal and plant tissues, secretions and excretions such as animal manures, composted vegetable material, solids and effluents from animal or plant production and processing facilities, and unprocessed biosolids and effluent from sewage treatment facilities.

Soil conditioner

A non-nutrient substance added to a fertiliser, or applied to land by itself, that alters the physical/structural characteristics of the soil by

- (i) altering the air or water retention capacity;
- (ii) encouraging flocculation;
- (iii) discouraging compacting;
- (iv) increasing the biological activity of soil; or
- (v) facilitating air circulation and drainage.

1.3 Subgroups of fertilisers

The fertiliser group of agricultural compounds is made up of substances or products that are used to encourage plant growth either by the provision of nutrients in particular or by optimising the chemical, physical or biological characteristics of soil.

For the purposes of the ACVM Act, the fertiliser group of agricultural compounds comes under the category of plant compounds because the products are used in the management of plants. Although some fertilisers are used to supply nutrients to animals (e.g. fertilisers containing selenium), the nutrients are absorbed by plants as an intermediate step. Such products are still included in the fertiliser group (plant compound) rather than in the veterinary medicine group of agricultural compounds.

The fertiliser group is divided into three subgroups, based on the intended effect of using the substance or product:

- fertilisers — used to provide nutrients to encourage the growth and health of plants;
- fertiliser additives — used to adjust the chemical or biological characteristics of soil to facilitate the uptake and use of nutrients; and
- soil conditioners — used to adjust the physical characteristics of soil.

These subgroups are not mutually exclusive. Products may be combinations of the subgroups. A product may have a fertiliser component that provides nutrients, but it may also have one or more fertiliser additives, such as lime, to improve the uptake of the nutrients. This combination may also be added to one or more soil conditioners such as compost or vermiculite and sold as a multi-purpose product. In some cases plants may be managed without contact with soil (i.e. hydroponics), and fertilisers and/or fertiliser additives are added to water as the media in which the plants are grown.

Because the risks posed by each subgroup are slightly different, the regulatory expectations for each subgroup are presented separately in this standard. It should be noted that subgroup combinations can have cumulative regulatory expectations.

Fertilisers include both inorganic and organic components. They may be in either solid or liquid form and may be applied to the soil or to plants as a foliar spray or used in water in which plants are grown. They all share the same intent, which is to facilitate the growth and health of plants by providing either a comprehensive or selective range of common and trace elements as nutrients. The subgroup may include fertilisers derived from animal material (blood and bone meal, fish meal etc.) and plant material (composted plant material, plant oils or infusions, seaweed etc.) as well as the mineral- and chemical-based fertilisers (superphosphate rock, dolomite, urea, ammonia, elemental sulphur, mineral salts etc.).

Fertiliser additives include substances that are used to facilitate the uptake and use of plant nutrients. They may include nutrients such as calcium, but their intended action is to modify either the ingredients in fertilisers or the chemical characteristics of the soil. The most common example is lime as a pH modifier. The subgroup also includes micro-organism cultures used to adjust the biological activity of the soil to enhance the uptake and use of nutrients.

Soil conditioners include substances that are used to modify the physical/structural characteristics of soil to increase or decrease its capacity to retain water, circulate air, prevent compacting or cause flocculation. Common soil conditioners are clay, sand, vermiculite, and other mineral components of soil. This subgroup also includes the organic constituents of soil such as humus and less decomposed plant material. These natural constituents of different types of soils when sold as bulk commodities are not considered to be agricultural compounds. Therefore, for the most part, soil conditioners are not relevant to this standard except for the few cases where some are sold as trade name product agricultural compounds.

Special consideration is given to biological wastes that are converted into either fertilisers or soil conditioners. If sufficient processing and quality control is applied during the manufacturing process, the wastes are considered to have achieved the status of agricultural compound products with a specified formulation and analysis of contaminants. If not, they must be considered to still be wastes.

As a general rule the ACVM Group categorises products in the fertiliser group of agricultural compounds according to the claims made about the products. For example, a compost product may be sold as a soil conditioner to increase the capacity of soils to retain moisture. The same product would be categorised as a fertiliser if it were claimed that it could be used as a source of nutrients. Regulatory requirements for each subgroup will be imposed if claims relating to that subgroup are made.

By themselves, soil and its components, water and any artificial substrates on which plants are grown are not considered to be agricultural compounds. However, they may be included if claims of a fertiliser or fertiliser additive are made.

1.4 Regulatory control of substances or products in the fertiliser group offered for sale

A relatively large commercial fertiliser industry markets recognisable brands of bulk or bagged and labelled products. However, the products in the fertiliser group of agricultural compounds can be formulated or manufactured relatively easily from simple, readily available chemicals and materials, some of which are common wastes. Consequently, it is common for individuals to compound their own combinations of plant nutrients (fertilisers), fertiliser additives and soil conditioners. Although these formulations are often used by the person compounding them, there is also a significant cottage industry trade.

There is also considerable trade in generic chemical substances. No fertiliser or fertiliser additive type claims are made by the person selling the substances, but there is readily available information in the public domain that encourages their use as fertilisers or provide directions on how they can be used as fertilisers.

The need for, and nature of, regulatory control varies with the kind of product and the potential for harm. Products that are offered for sale have a much wider distribution and, consequently, a greater impact than formulations that are compounded for personal use.

Products used on food crops that are commercially traded will also have a greater impact than formulations used on ornamental plants and home fruit/vegetable gardens. Therefore, regulatory control depends on:

- the type of product;
- whether or not it is traded; and
- what kinds of plants it is used on or what plants will be grown in the treated soil or water substrate.

1.5 Regulatory control of substances or products in the fertiliser group not offered for sale

There is an exemption from registration of agricultural compounds in Schedule 1 of the Agricultural Compounds and Veterinary Medicines Regulations 2001 to allow people to use, without registration, fertilisers and fertiliser additives on plants owned by that person and on soil owned or occupied by that person. This exemption from registration does not alleviate that person of any responsibility or obligation under any other legislation such as the Resource Management Act 1991 or the Hazardous Substances and New Organisms Act 1996, nor does it allow the fertiliser or fertiliser additive to be sold (see 'Sale' in Glossary) to any other person. The exemption does not allow non-fertiliser claims (e.g. pest management claims) to be made

While this exemption from registration provides an opportunity for people to compound and use their own fertiliser or fertiliser additive formulation, there is always the possibility

that it may have been contaminated with dangerous substances, pathogenic micro-organisms, animal or plant pests or weeds. These could cause harm to animals exposed or result in violative residues in the animal products (meat, milk, eggs, honey etc.) or plant produce harvested from those animals or plants. It could also contribute to the spread of pathogens, animal or plant pests or weeds. While there is no need to register the formulation, there is a moral obligation to ensure that it will not cause negative effects. There are also statutory obligations to:

- protect the welfare of the animals; and
- ensure that there are no violative residues in the animal products or any produce from any plants exposed.

There may also be consequences if the trade and use of products negate or hinder the outcomes of national or regional pest management strategies. Parties should take due care to determine the production history of the materials in their formulation prior to applying them to plants or soil. For example, there may be a history of contamination or intentional application of chemicals or pesticides to plant material. Appropriate steps must be taken to comply with the *ACVM Standard for Own Use of Agricultural Compounds*.

1.6 References

Agricultural Compounds and Veterinary Medicines Act 1997
Agricultural Compounds and Veterinary Medicines Regulations 2001
ACVM Standard for Good Manufacturing Practice
ACVM Standard for Own Use of Agricultural Compounds

2 REQUIREMENTS FOR FERTILISERS AND FERTILISER ADDITIVES

All products that are either fertilisers or fertiliser additives are exempt from registration under Regulation 9 of the Agricultural Compounds and Veterinary Medicines Regulations 2001 as long as the products comply with Schedule 5 of those Regulations. In effect, Regulations place requirements on the import, manufacture and trade in fertilisers and fertiliser additives.

The ACVM Group considers that raw and composted biological wastes do not have sufficient processing and quality control to be considered trade name products manufactured to the principles of good manufacturing practice. In many cases they do not have a consistent formulation, and the control over the sources of materials is minimal. There is insufficient analysis and control of contaminants such as heavy metals or chemicals. Consequently, they must still be considered to be waste material and their use should be subject to regulatory control under the Resource Management Act 1991. This restricts their use to circumstances when proper local government approval has been issued.

The ACVM Group and the greater New Zealand Food Safety Authority (NZFSA) have serious concerns about the widespread distribution of biological wastes for both food safety and biosecurity reasons. It is expected that local government bodies will apply technically sound rules to govern the application of biological wastes to land.

2.1 General requirements for manufacture

Schedule 5 specifies the requirements that must be met when manufacturing a fertiliser or fertiliser additive. They must be supplied with a label containing the following information:

- (a) trade name:
- (b) the name and address of the producer, if applicable:
- (c) the name and address of the manufacturer, if applicable:
- (d) batch number, if applicable:
- (e) the order number, if applicable:
- (f) the date of delivery, if applicable:
- (g) nutrient content and modifying pH value, if applicable:
- (h) details of any precautions to be taken to prevent or manage risks described in section 19 of the Act when being used, particularly potential hazards to animals exposed to them:
- (i) directions for use.

They must be fit for the purpose specified in the directions for use. They are fit for their purpose only if they are used as recommended and do not do any of the following:

- (a) produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment:
- (b) cause pain and distress in animals due to toxic reactions or physical damage:

- (c) contain micro-organisms at pathogenic levels or any other plant or animal pest that is likely to promote disease or pest transmission:
- (c) have a selenium content that would result in the application of selenium as sodium selenate at a rate exceeding 10 grams per hectare.

This means that the manufacturer must ensure that the product is fit for the purpose specified in the directions for use. The manufacturer must control the selection and acquisition of raw materials and formulate the product in such a way that there will not be:

- violative residues;
- toxic or physical harm to any animals exposed to the treated land or plants grown on that land (or in the water substrate in the case of hydroponics); or
- any micro-organisms or plant or animal pests that are likely to promote disease or pest transmission or weeds specified in national or regional control programmes.

Selenium is mentioned in particular in Schedule 5 as a previously regulated measure of application of that element that is likely to be fit for purpose. However, the manufacturer must ensure that any other ingredient in the product is included at safe and appropriate levels, given the recommended use.

Products manufactured in the fertiliser group are not subject to good manufacturing practices (GMP) approval from the ACVM Group. However, there is an expectation that, when manufacturing products in the group, the principles of good manufacturing will be used to the extent that is appropriate to minimise the hazards that are either present or introduced in the manufacturing process. The ACVM Group will investigate suspicions and allegations of non-compliance with Schedule 5 and may require a remedial action inspection programme and may prosecute where there are breaches in the Regulation.

Export-only fertilisers or fertiliser additives are not subject to this standard, Regulation 9 or Schedule 5. However, they must be either:

- identified as 'export-only' and manufactured separately; or
- manufactured in compliance with this standard and the Regulations.

2.2 Specific requirements for manufacture

2.2.1 Responsibility

When the manufacturer is the producer of the product, he/she is responsible for ensuring that the product complies with the prescribed requirements for fertilisers or fertiliser additives exempt from registration. If the manufacturer is preparing the product under contract to the producer, then the producer is responsible and must make the product specifications and manufacturing directions clear in the contract. If there is any variation to this, the areas of responsibilities must be documented in the manufacturing specification. The following requirements refer to the manufacturer as the producer. If this is not the case, the requirements should be read as pertaining to the person specified as responsible.

2.2.2 Labelling

The manufacturer must ensure that the product is adequately labelled when it is offered for sale. The 'label' is all the information provided with the product at the point of sale and is not limited to the information on or attached to the package.

Bulk fertilisers or fertiliser additives must be sold with the prescribed information. It is acceptable for the information relating to bulk product to be provided in a detached document, but it must be provided with the consignment. The information must be presented to the person with the overall responsibility for the application of the fertiliser or fertiliser additive. This may mean that, in a vertically integrated operation or in one with multiple locations, the information may be provided to a person responsible who specifies the application instructions to the individual operators if the operators are only following that person's instructions.

There must be adequate information to facilitate investigations of adverse events or non-compliance. The contact information should reflect the arrangements in the contract and identify the person(s) responsible for the product. It must also provide a batch number, delivery reference or both so that the actual product used can be related to the manufacturing process. What is appropriate may vary for different kinds of products. What is provided should be what is commonly used in the manufacture, distribution and sale for that kind of product.

There must be adequate information to allow the product to be used safely and appropriately.

Information on ingredients must be at least as detailed as is considered common best practice in the fertiliser industry for that kind of product. It is expected that the industry sector, in consultation with regulators and consumers, would determine what common best practice is for labelling ingredients. Manufacturers would be expected to provide at least that level of information.

2.2.3 Production to specifications

The ACVM Group will not specify minimum levels of nutrients such as nitrogen, phosphorous or potassium, but it will expect manufacturers to specify levels (as per industry practice) according to the master formulation for the product. The fertiliser or fertiliser additive when offered for sale must conform to the master formulation and have been manufactured according to the manufacturing specifications.

The manufacturer must have checks in place to ensure that the raw materials used to manufacture the product were fit for purpose, either:

- being free of hazards; or
- subsequently processed and incorporated into the product so that they do not cause toxicity, physical damage, violative residues or are a source of pathogenic organisms or animal/plant pest or weeds specified in national or regional control programmes.

The manufacturer must document the production process, specifying actions taken during manufacture to ensure that the product meets specifications and is fit for purpose. Areas of responsibility must be specified, and production systems and instructions kept current.

It is expected that the manufacturing process (from specification of master formulation through packaging, labelling and dispatch) would be subject to a documented quality system, using controlled copies of the quality system or operational manual if necessary.

There must be contingency plans in the quality system of operational manuals to recall non-compliant product or mitigate adverse effects.

As stated above, ensuring that products meet the nutrient requirements of plants is not an area of regulatory control under the ACVM Act, so no requirements are set governing the level of nutrients that must be included for plant growth or health or to justify the status as a fertiliser. Failure of the product to achieve claims is not relevant to the ACVM Act, but it may be an issue in regard to the Fair Trading Act 1986.

The ACVM Group will expect to see content information to ensure the product is what it claims to be and can be used safely and appropriately. Content assays should be carried out in regard to hazards but quality control of levels of nutrients to master formulation specifications is not an ACVM Act issue. This is particularly relevant to products made from animal or plant material of variable nutrient content. The manufacturing process must control dangerous ingredients, contaminants, micro-organisms, pests and weeds but, from an ACVM Act perspective, control of nutrient levels is irrelevant.

Although it may be difficult to manage the quality of trade name products that may include organic wastes (green wastes, sewage, wastes from facilities processing animal products), such products most comply with this standard. The same is true for similar products traded at a cottage industry level. It is acceptable to apply minimal contaminant analysis in cases where the source and treatment history of the raw materials used are well known. However, if raw materials are collected from multiple uncontrolled sources, it is expected that contaminant analysis and management are routine components of the manufacturing process.

2.3 Importation

Any fertiliser or fertiliser additive imported into New Zealand must be registered unless the product complies with the prescribed requirements listed above.

Importers are responsible for ensuring that the product and its manufacture comply with the Regulations and this standard. They must be able to show how they confirmed compliance. They must be able to confirm that the manufacturing process was equivalent to what is expected of similar products manufactured in New Zealand.

Where necessary, manufacturers must adjust the information provided with the imported product to meet the prescribed labelling requirements. Because there is no producer or manufacturer in New Zealand, the label must specify the importer as the person responsible for the product. The importer will be held liable if the product is found not to comply with the prescribed requirements.

2.4 Trade

Manufacturers must ensure that fertilisers and fertiliser additives and their labelling comply with the prescribed requirements and meet this standard. Therefore, if manufacturers have met the statutory obligations, the products should be fit for purpose and be labelled appropriately. Persons trading in such products should not alter the products in any way and must ensure that the information provided by the manufacturer is passed on to the purchaser.

If traders add any ingredients or combine different products, they will be considered to be the manufacturers of new products and will be subject to the manufacturing requirements above. Mixing of products or making additional claims may make the exemption from registration irrelevant, and it will be up to the trader to comply with any consequential regulatory requirements.

If products are altered, repackaged or relabelled by the trader, then the products are no longer the ones provided by the manufacturer. The trader must take full responsibility for any non-compliance in regard to the altered products unless the trader can show that the alterations were not the cause of the non-compliance.

Traders must not misrepresent products in any advertisement or promotion. They must not make additional claims. They must not repackage or relabel products and represent them as the original product unless they do it according to the recommendations of the relevant manufacturer.

Traders will be expected to have quality systems that maintain the identity and integrity of the products they sell. They will be expected to maintain adequate records to address any suspicions or allegations of non-compliance.

2.5 Use

Fertilisers and fertiliser additives should be used as recommended. Application of fertilisers or fertiliser additives to land may require prior approval under the Resource Management Act 1991. No approvals issued or conditions imposed under the ACVM Act necessarily alter any requirements or obligations under any other legislation.

Recommendations about a product made by parties other than the proprietor or a trader (i.e. parties with no vested interest in the sale of the product) are not considered by the ACVM Group to be advertisement or promotion for the purposes of this standard. Under these circumstances, if the product is used as recommended and results in an animal welfare or violative residue negative effect, regulatory action may be taken against the user.

3 REQUIREMENTS FOR SOIL CONDITIONERS

3.1 General requirements

As stated above, soil conditioners that are common constituents of soils (such as clay, gravel, sand, humus and water) are not considered to be agricultural compounds. However, when the organic components are in the form of compost, potting and seedling mix products, sold in bulk or as bagged and labelled product with fertiliser or fertiliser additive type claims, they are considered to be agricultural compounds.

Soil conditioners with fertiliser or fertiliser type claims that are covered by an exemption from registration for plant material must not be supplemented with any component other than plant material or constituents of soil (see examples above). The ACVM Group considers that soil conditioners that are raw or composted biological wastes should be regulated via the Resource Management Act 1991 as is the case for fertilisers and fertiliser additives that are raw or composed biological wastes.

3.2 Manufacture, importation, trade and use

The requirements for manufacturing, importing, trading and using soil conditioners are the same as for fertilisers and fertiliser additives. Soil or common constituents of soil are not considered to be agricultural compounds when sold as such. The exceptions are formulations manufactured from animal or plant material and sold as trade name product agricultural compounds (e.g. composts, compost fertiliser mixes, potting mixes etc.). If such products are sold for use by anyone other than the person who formulated them, they must be manufactured and presented for sale in a manner that ensures the product:

- is what it is claimed to be;
- is consistent with the manufacturing specifications and hazards are eliminated or controlled; and
- is labelled with sufficient information to direct its safe and appropriate use.

In other words they must comply with the manufacturing specification of this standard. Products manufactured from organic wastes that are unable to meet these outcomes are considered to still be organic wastes.

If soil conditioners are manufactured and used by the same person on their own land and plants, then the formulations and their use must comply with the *ACVM Standard for Own Use of Agricultural Compounds*.

4 REQUIREMENTS FOR RAW AND COMPOSTED ORGANIC WASTES

Raw and composted organic wastes are substances that are made from wastes from other industries (meat and milk processing operations, agricultural and horticultural operations, domestic or industrial waste management operations). 'Raw' means that no processing has occurred and 'composted' means that a level of intentional decomposition has been allowed to occur but no further control of formulation or management of physical, chemical or biological contaminants has been carried out.

Once raw and composted organic wastes are processed to the point where they have a consistent and predictable formulation with adequate and reproducible control of chemical and biological contaminants, they are considered to be products that can be regulated under the ACVM Act. If that level of control over manufacturing is not achieved, the products, which may be marketed as fertilisers, fertiliser additives or soil conditioners, are actually wastes and their use is subject to regulatory control under the Resource Management Act.

It is expected that those parties involved in the production and marketing of waste products will develop codes of practice that will meet the requirements of regulatory control under the Resource Management Act. The NZFSA will monitor that regulatory control and make submissions to the responsible regulators if it has concerns that the application of wastes to agricultural land appears to be introducing hazards into domestic or export food or primary produce.

Agricultural Compounds and Veterinary Medicines

Glossary of common terms

Advertisement

Any publication to the community or to any section of the community of any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device, used to promote the sale of any agricultural compound. 'To advertise' has a corresponding meaning.

Agricultural compound

Any substance, 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, place, or water on or in which the plants and animals are managed, for the purposes of:

- a) Managing or eradicating 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 purpose of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 by Order in Council.

Animal

Any living stage of any member of the animal kingdom except human beings. It also does not include invertebrates unless specified as in the case of honey bees.

Animal material

Any live or dead animal, or any tissue or other material taken or derived from an animal.

Approval

Means approval by the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the New Zealand Food Safety Authority.

Code of practice

Any document developed to specify the means by which parties meet the requirements in a standard. A code may be approved in accordance with section 28 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, but does not have to be approved unless specified in the conditions of product registration or any product specific approval.

Compounding order

An instruction from a veterinarian to a manufacturer or contracted compounding pharmacist, detailing the formulation of a specially compounded medicinal preparation and any additional details on the method of compounding, packaging and labelling.

Control

To maintain full responsibility for and direction of the actions of others, and relates to the control of specified persons by persons approved or licensed by the ACVM Group to manufacture, trade in or use agricultural compounds or veterinary medicines.

Controlled copy

An operational or quality control reference document for which:

- responsibility for maintenance, updates, and changes will be undertaken by a limited and defined group of people; and
- all changes and updates will be recorded in writing and maintained for audit.

Direct management

Direct management includes any treatment used on/in the animal or plant; or any treatment that will be in direct contact with the animal or plant; or any treatment where the animal remains in the water/on the land during the treatment period; or when the animals are reintroduced to the water or land and the agricultural compound is still present.

Dispensing

To supply agricultural compounds or veterinary medicines as per instructions specified in a purchase/supply order, compounding order, veterinary prescription or veterinary authorisation.

Label

Any written, pictorial, or other descriptive matter under which the trade name product is sold and which purports to give some information about the agricultural compound or veterinary medicine. Includes any information that must be provided with the product at the time it is supplied.

Label content

The intended written, pictorial, or other descriptive information that can be provided with a product because it is consistent with and not beyond or in excess of what is permissible under the current approval for that product. The label content must be approved by the ACVM Group.

Prescribing

The act of deciding and specifying the appropriate veterinary medicine and treatment regime.

Prescription

A documented instruction to an approved trader in veterinary medicines from a veterinarian specifying:

- a particular veterinary medicine;
- an animal or group of animals to be treated;
- a dosage and frequency; and

- instructions to be provided to the named person responsible for the animal(s) regarding warnings and/or associated care.

A prescription is required for the purchase of a registered PAR product by a person who is not a veterinarian. Only veterinarians may issue a prescription for a registered PAR product. A prescription may be issued for but is not required for the purchase of a veterinary medicine that is not a PAR product.

Prescription animal remedy (PAR) veterinary medicine

A veterinary medicine registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 with a condition limiting sale to:

- an approved trader in prescription animal remedies;
- a veterinarian currently registered under the Veterinarians Act 1994; or
- a person in possession of a relevant, *bone fide* veterinary prescription or authorisation from a veterinarian currently registered under the Veterinarians Act 1994.

Product specific approval

That part of an ACVM registration of an agricultural compound or veterinary medicine trade name product that specifies the particular use requirements for that product in regard to manufacture, importation, sale, establishing control, identifying treated plants or animals, avoiding violative residues, notifying purchasers or processors, etc.

Promotion

To encourage the sale of an agricultural compound or veterinary medicine trade name product by any means, including advertising.

Proprietary trade name product

An agricultural compound or veterinary medicine marketed under and protected by a registered trade name.

Relabelling

To transfer the relevant label information (provided with the product before breaking down and repackaging) to the package or container in which the agricultural compound or veterinary medicine trade name product is supplied for use.

Sale

Includes barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale; and also includes:

- a) delivering or disposing of by way of gift, loan, or otherwise; and
 - b) giving or distributing, in the course of business, as a sample or otherwise, without charge.
- ‘General sale’ means to make available to the public at large.

Separating off portions of trade name product

To adjust the size, volume, number or weight of an agricultural compound trade name product and to place into an alternative package or container (should also have an alternative label).

Trade

Trade in agricultural compounds or veterinary medicine trade name products includes general sale and sale to specified/approved persons (wholesale and retail sales transactions as well as distribution, transport and storage). It also includes gifting or offering as samples as stated in the definition of sale.

Trader

Any person/corporate body/company who sells agricultural compounds or veterinary medicines. Traders can include, importers, product registrants, manufacturers, distributors, wholesalers and retailers, veterinarians and agricultural consultants, if they carry out any of the activities listed in the definition of sale above.

Veterinarian

A person currently registered as a veterinary surgeon under the Veterinarians Act 1994.

Veterinary authorisation

A documented approval from a registered veterinarian to a person to purchase and hold particular PAR veterinary medicines in anticipation of:

- their incorporation into other products (e.g. animal feeds) to be used under prescription;
- or
- their use under operating instructions issued by a registered veterinarian.

Veterinary consultation

In relation to the administration of or the prescribing of any PAR veterinary medicine by a veterinarian to, or in respect of, an animal means:

- (i) an examination of that animal, which is an animal in the immediate care of that veterinarian; or
- (ii) the obtaining by that veterinarian of sufficient information about that animal, which is an animal in the immediate care of that veterinarian, to enable that veterinarian to make an informed decision with respect to the administration or prescribing of a PAR veterinary medicine to, or in respect of, that animal.