

Products regulated under the ACVM Act

ACVM guideline (July 2020)

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1. Introduction

In New Zealand the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 is the statutory basis for regulating products that are used on animal or plants. It is illegal to import, manufacture, sell or use an agricultural compound product (see definition below) if that product has not been properly authorised under the ACVM Act. The ACVM Team of New Zealand Food Safety, Ministry for Primary Industries, is the Government body that administers the ACVM Act and issues authorisations.

Kinds of authorisation

These guidelines have been prepared to help you work out if your product is regulated under the ACVM Act and, if so, what kind of authorisation is required before it can be imported into, manufactured, sold or used in New Zealand. Under usual circumstances, there are two main kinds of product authorisation. Some products require registration. Other products fit into a category that is exempt from registration. This document focuses on these exemptions from registration.

The exempted groups of products are listed and defined in Schedule 2 of the [Agricultural Compounds and Veterinary Medicines \(Exemptions and Prohibited Substances\) Regulations 2011](#). Use the Regulations as the legal point of reference.

If your product fits the definition of a compound that is exempt from registration, it can be imported, manufactured, sold or used without any additional regulatory approval. Because these definitions are general, they are open to interpretation. You can draw your own conclusion as to the status of your product. However, if you interpret the definitions incorrectly, you could end up breaking the law.

Use these guidelines and, if in doubt, ask the ACVM Team for a class determination (approvals@mpi.govt.nz). (There is a fee for this service.)

What is ‘class determination’?

Class determination is a process used by the ACVM Team to determine if your product is an agricultural compound (such as a veterinary medicine/agricultural chemical/vertebrate toxic agent/fertiliser/oral nutritional compound) under the ACVM Act and, if your product is an agricultural compound, determine whether it is exempt from registration.

It is important to note that products classified as exempt from the requirement for registration have not been “approved”. The determination is the opinion of the ACVM Team regarding the status of the product under the ACVM Act and Regulations and is based solely on the information provided with the application.

2. Is my product an agricultural compound?

The first consideration is whether or not your product is an agricultural compound. If it is not, the ACVM Act is not relevant.

Definition

The definition of an agricultural compound in the ACVM Act is: “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—

- Managing or eradicating pests, including vertebrate pests; or
- Maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
- Fulfilling nutritional requirements; or
- The manipulation, capture, or immobilisation of animals; or
- Diagnosing the condition of animals; or
- Preventing or treating conditions of animals; or
- Enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
- Marking animals;

and includes any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest treatment of raw primary produce, and anything intended to be used as feed for animals: 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”.

Interpretation

We use the following principles to interpret this definition.

1. *The product must be a compound/substance rather than an object when sold.*

Products that are sold as inert objects are not included in the definition of substances. For example, devices and equipment used on animals (such as bandages, sutures, bone pins) are not considered veterinary medicines except where the device (to be used on an animal or to which an animal is intentionally exposed) cannot be separated from a veterinary medicine. In such cases, the device/equipment will be considered a veterinary medicine product in toto (e.g. a bolus that delivers a set dose of a medicine, or a medicated bandage impregnated with a substance intended to manage the animal). A fly swatter is not an agricultural compound even though it is used to control pests because it is an object, not a compound.

2. *The product must be used to manage the animal or plant.*

Management refers to:

- applying the substance directly in, on or to the animal or plant; or
- applying the substance to the environment including the land and water of the animal or plant, or in preparation for the introduction of the plant or animal.

3. *The classification of a product as an agricultural compound is made on a case-by-case basis depending on the stated usage and/or purpose.*

To be an agricultural compound, the reason why a product is to be used must fit one of the purposes listed in the definition given above. Substances used to manage animals or plants to achieve an outcome other than one of the listed purposes are not agricultural compounds. For example, substances administered to an animal to change an aspect of the animal solely for the benefit of humans sharing their environment (e.g. reducing faecal odour) are not agricultural compounds. Similarly substances applied to plants for the benefit of humans, such as making houseplants look shinier, are not agricultural compounds.

4. *Possible purposes are not usually relevant.*

A product is not an agricultural compound just because it could be used as one. The important factor is the stated or intended purpose and this principle usually applies. However, certain ingredients are known to have only agricultural compound uses. These types of ingredients attract a higher level of New Zealand Food Safety (NZFS) interest when they are imported and offered for sale.

5. *Definition is not based on mode of action.*

Substances that after application have only a mechanical mode of action are considered agricultural compounds. For example, tissue glue for animals or acrylic paint for pruning wounds on plants are

substances that work via a mechanical mode of action, but because they are not inanimate objects when applied to the animal or plant and are intended to manage the animal or plant directly, they are agricultural compounds even though inanimate objects that would achieve the same purpose (e.g. nylon sutures and plastic wraps) are not agricultural compounds.

Examples

Following these principles, these types of products are agricultural compounds:

- products used to manage disease in animals
- products used to provide nutrients to animals or plants
- products used to manage pests on plants
- products used in the management of turf and amenity or ornamental plantings
- products used to control vertebrate pests.

These products are NOT agricultural compounds:

- products intended for use in an industrial or recreational context (such as for control of wasps to prevent nuisance to humans in a picnic area or for control of weeds at a factory site or parking lot)
- household and personal invertebrate pest control products (such as household fly sprays) for human health purposes
- products used solely for public health invertebrate pest control.

What about air and water?

Air and water are not considered agricultural compounds in their own right. For example, irrigation water is not an agricultural compound. Products added to or intended to treat air or water are not agricultural compounds unless a specific claim is made that the product is intended to treat air or water to help manage animals or plants. For example, water treatment products used in equipment cooling towers to keep the equipment from overheating are not agricultural compounds. Similar products used to keep aquaculture water filters clean are agricultural compounds because the purpose of filtering the water is to have clean water for animals or plants. In hydroponics, filters which remove bacteria for human health purposes (e.g. *E.coli*) are not agricultural compounds, but if the filters are intended to remove bacteria that would affect the plants, then they are agricultural compounds.

3. What is the next step?

If you have determined that your product is an agricultural compound, the next step is to decide what kind of authorisation it must have. If your product does not fit the definition of one of the product

groups exempt from registration (see decision trees below), it probably requires registration. Information and application forms for registration are on our website.

If your product fits an 'exempt' definition, you do not need any additional regulatory approval. You can import*, manufacture, sell or use your product without additional approval, but you must comply with the general and specific requirements imposed by the Regulations. Refer to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 (link above). To help you understand these legal requirements, see the ACVM guideline: *Obligations under the ACVM Regulations*.

* For **commercial** imports of exempt products you need a class determination letter to present to border officials before the product will be released. For other imports, a class determination letter will facilitate importation. This is an administrative rather than a legal requirement. (There is a fee for this service.)

4. Product groups exempt from registration

The agricultural compound product groups in the decision trees below are exempt from the requirement to be registered. The product groups are listed in the same order (with the same number) as in Schedule 2 of the Regulations. These exemptions are not mutually exclusive. For example, an oral nutritional compound (entry 22) could also contain herbal preparations (entry 13).

Multiple purposes/claims

Consider your product in light of the description. If your product is intended to be used for more than one purpose, each purpose must be in one or more of the exemption entries for the exemption from registration to apply. For example, if your product is a pet food (entry 22), you can also make a claim that it will adjust the pH of urine of the pet beyond the physiological normal range to prevent the development of kidney or bladder stones (entry 19) but you cannot claim that the pet food helps to manage or treat arthritis. If you make this type of therapeutic claim, your pet food would require registration because it is no longer just a pet food—it would be classed as a veterinary medicine.

Making multiple claims for your product may exclude it from any particular exemption. However, Regulation 6 allows combinations with aspects of the product relating to different exemptions. For example, an invertebrate attractant (entry 4) may be combined with an invertebrate mating disruptor (entry 5).

If each of the claims you make about your product is covered by an exemption, then collectively the product can still be exempt from registration. **If any agricultural compound use of your product is not covered by an exemption, the product is not exempt from registration.**

The particular active ingredients and excipients, such as carriers or preservatives, do not jeopardise the relevance of an exemption, unless the particular ingredient is on the list of flagged compounds that are known to have only agricultural compound uses (such as glyphosate).

Non-agricultural compound claims

The exempt status of a product is not jeopardised by any non-agricultural compound claims, such as a public health claim. You may make claims that your product also cleans windows or gets rid of annoying house flies and not jeopardise its exempt status. Be aware that such claims may make your product subject to other legislation, but that is not relevant to a class determination under the ACVM Act.

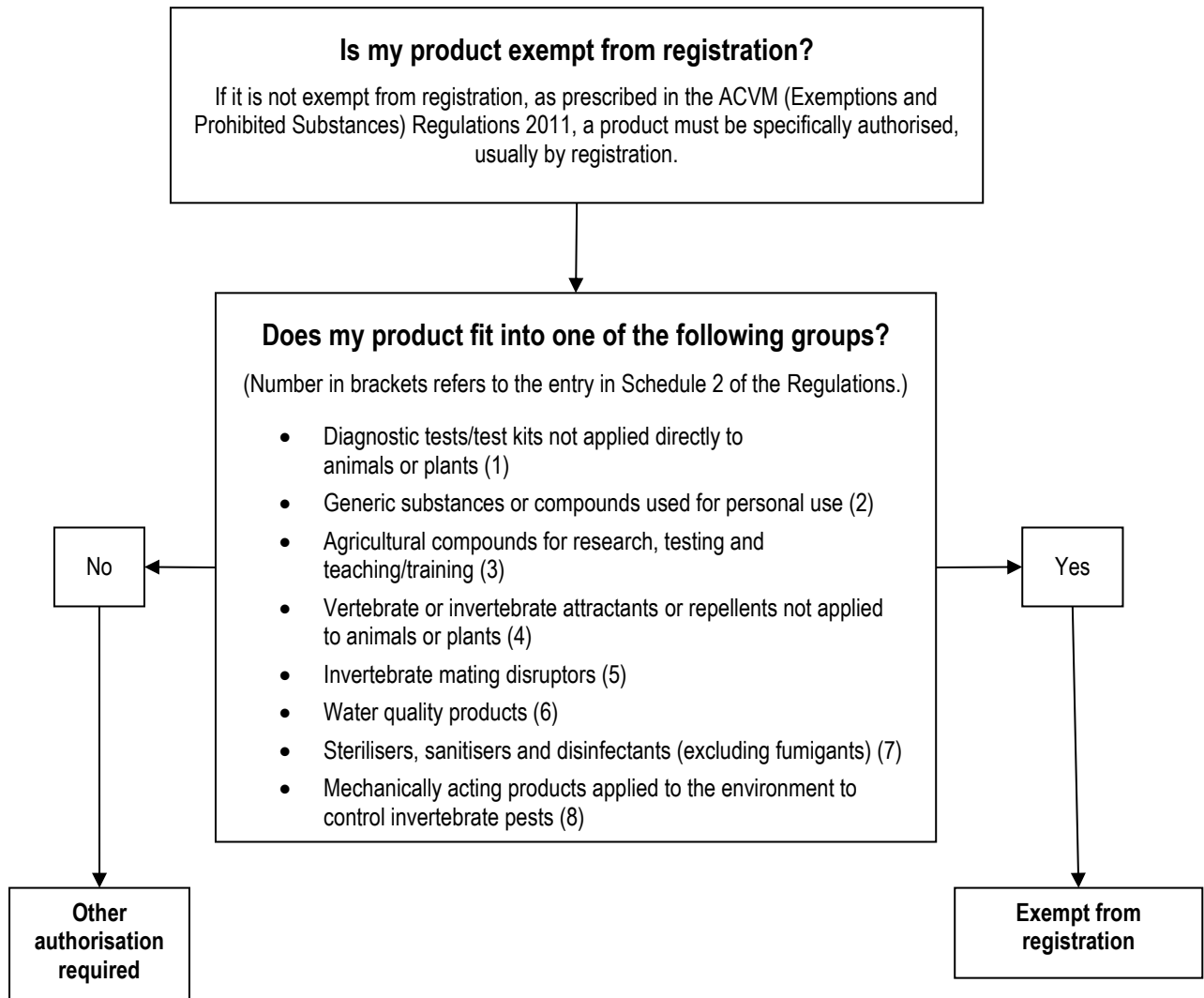
You need to consider your product and the claims you want to make about it in light of the entries in the Regulations. Most of the exemptions are based on the stated/intended use. However, you will see that a few exceptions (entries 2, 9, 10) relate to the person using the product rather than the use.

To help you find the exemption that might fit your product, the product groups are listed in three decision trees:

- Products that could be used for the management of either animals or plants
- Products that are used to manage animals
- Products that are used to manage plants.

These decision trees provide the categories of exemptions, but if you are uncertain ask the ACVM Group for a class determination (approvals@mpi.govt.nz). (There is a fee for this service.)

Class Determination of Product Groups for Management of Plants and/or Animals



Class Determination of Product Groups for Management of Animals

Is my product exempt from registration?

If it is not exempt from registration, as prescribed in the ACVM (Exemptions and Prohibited Substances) Regulations 2011, a product must be specifically authorised, usually by registration.



Does my product fit into one of the following groups?

(Number in brackets refers to the entry in Schedule 2 of the Regulations.)

- Human medicines used by veterinarians (9)
- Compounded veterinary preparations used by veterinarians (10)
- Oral and topical homeopathic veterinary medicines (11)
- Topically applied veterinary medicines to treat or prevent minor wounds or skin abnormalities; to clean the skin, coat, teeth or hooves; to maintain the skin, coat or hooves or to disguise odours (12)
- Oral and topical herbal preparations (13)
- Animal markers (14)
- Gastrointestinal adsorbent or protectant antidiarrhoeal preparations (15)
- Local surface acting laxatives and lubricants administered orally, rectally or to the vulva or vagina of animals (16)
- Non-medicated moist or dry poultice preparations used on animals (17)
- Cauterising preparations used or applied superficially to animals (18)
- Oral urinary tract modifiers (acidifiers and alkalisers) (19)
- Respiratory tract modifiers (expectorants and cough suppressants) (20)
- Agricultural compounds used to extend animal semen or to be used as media for animal sperm, cells, ova, and embryos (21)
- Oral nutritional compounds (pet food, animal feeds) (22)
- Oral gastrointestinal acting microflora-enhancing compounds (OGAMEC) (23)
- Semiochemical behavioural modification preparations (24)
- Biologically active environmental invertebrate pest control agents for non-food producing animals (25)
- Topically absorbable animal nutrients (26)
- Topically applied non-irritating substances with a mechanical mode of action (27)

No

Yes

**Other
authorisation
required**

**Exempt from
registration**

Class Determination of Product Groups for Management of Plants

Is my product exempt from registration?

If it is not exempt from registration, as prescribed in the ACVM (Exemptions and Prohibited Substances) Regulations 2011, a product must be specifically authorised, usually by registration.

Does my product fit into one of the following groups?

(Number in brackets refers to the entry in Schedule 2 of the Regulations.)

- Disinfection or disinfestation of empty structures before plants or produce are introduced (28)
- Mechanical action to control invertebrate pests applied directly to plants or produce (29)
- Spray markers for plants (30)
- Agricultural chemical additives (31)
- Vertebrate or invertebrate repellents applied directly to plants (32)
- Vertebrate or invertebrate attractants applied directly to plants (33)
- Mating disrupters applied directly to plants (34)
- Protection of plants from climatological conditions, e.g. frost protectant, sunblocks (35)
- Home garden and commercial production of non-food crop plants (36)
- Homeopathic agricultural chemicals used commercially (37)
- Agricultural compounds used in the production of plant tissue cultures (38)
- Agricultural compounds (not containing biologically active ingredients) used to protect plant grafts or plant wounds (39)
- Agricultural compounds (not containing biologically active ingredients) used to provide a physical barrier to infestation or infection of plants (40)
- Agricultural compounds used in the post-harvest treatment of wood-producing crops (41)
- Fertilisers (42)
- Plant biostimulants (43)
- Soil conditioners (44)

No

Other
authorisation
required

Yes

Exempt from
registration

5. Substances prohibited in agricultural compound-based products

Agricultural compounds

In the ACVM (Exemptions and Prohibited Substances) Regulations 2011, the following substances are prohibited from use as agricultural compounds or as ingredients in agricultural compounds.

Aldrin
Chlordane
Chlordecone
DDT including DDD (also known as TDE) and DDE
Dieldrin
Technical endosulfan and its related isomers
Endrin
HCB (also known as hexachlorobenzene) except as an impurity in other active ingredients
HCH (also known as hexachlorocyclohexane or benzenehexachloride)
Heptachlor
Lindane
Mirex
Pentachlorobenzene
Pentachlorophenol and its salts and esters
Toxaphene

Veterinary medicines

Some New Zealand trading partners prohibit the use of certain substances in food-producing animals. Consequently, NZFS will not approve the registration of products containing these substances with label claims for use in cattle, deer, goats, sheep, llamas, ostriches, emus or fish unless their risks can be managed under the ACVM Act, particularly in relation to trade. The following substances fall into this category.

17 β -oestradiol and its esters
Arsenilic acid
Chloramphenicol
Chloroform
Chlorpromazine
Colchicine
Dapsone
Nandrolone
Nitrofurans (including, but not limited to, nitrofurazone, nihydrazone, furazolidone, furaltodone)
Nitroimidazoles (including, but not limited to, dimetridazole, ronidazole, metronidazole, carnidazole)
Substances with the pyrazolidone moiety within the chemical makeup (for example, but not restricted to, phenylbutazone, ramifenazone, dipyrone).