



Products regulated under the ACVM Act

ACVM guideline

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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 Group of the 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 different 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 Group for a class determination (approvals@mpi.govt.nz). (Fees apply.)

What is 'class determination'?

Class determination is a process used by the ACVM Group 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.

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 management¹ 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.

For example, bandages are used to manage animal wounds but they are not substances so they are not considered to be agricultural compounds unless they have a compound (such as an antibiotic or antiseptic) imbedded into them. 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 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 intended purpose of a product must fit one of the purposes listed in the definition given above.

3. 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. This principle usually applies. However, certain ingredients (such

¹ By 'direct management' we mean

- treatments on/in the animal or plant
- direct contact with the animal or plant
- the animal/plant remains in water/land during the treatment period
- when the animal/plant is reintroduced to the environment, the agricultural compound is still present and intended to have an effect on the animal/plant itself.

as glyphosate) are known to have only agricultural compound uses. These types of ingredients attract a higher level of MPI interest when they are imported and offered for sale.

4. Definition is not based on mode of action.

Even compounds that 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 compounds with a mechanical mode of action, but they are intended to manage the animal or plant directly. Therefore, they are agricultural compounds.

Examples

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

- products used to manage disease in animals
- products intended for use in the home garden and on commercial crops
- 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), provided they are not used on plants or animals
- 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.

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* (available on our website).

* For **commercial** imports of exempt products you need a class determination letter to present to border officials before the product will be released. This is an administrative rather than a legal requirement. (Fees apply.)

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, a topical veterinary medicine (entry 16) could also be an over-the-counter first aid preparation (entry 15).

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 25), you can also make a claim that it will adjust the pH of urine of the pet to prevent the development of kidney or bladder stones (entry 22) 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.

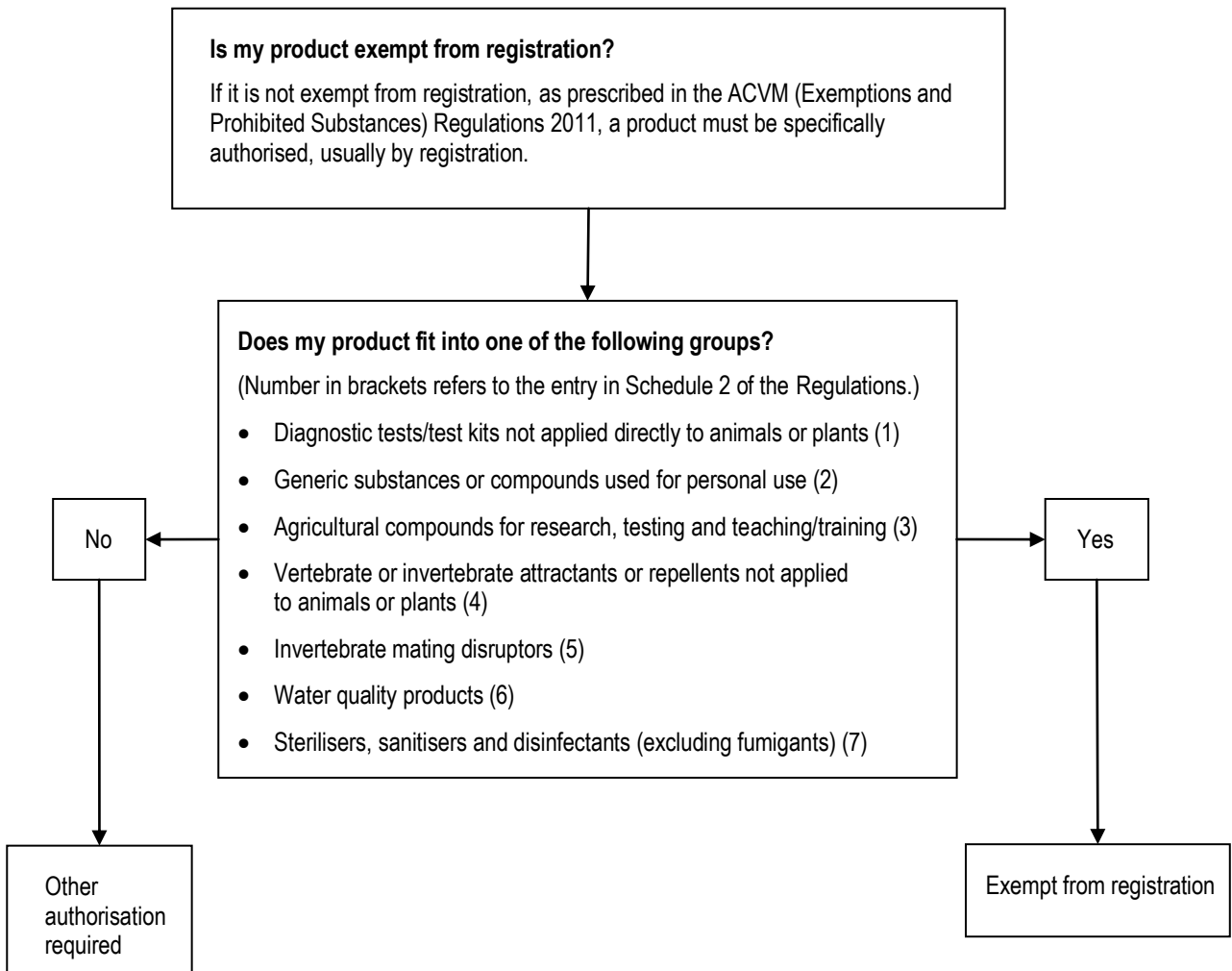
You need to consider your product and the claims you want to make about it in light of the entries in the Regulations. Most of the exemptions are based on the stated/intended use. However, you will see that a few exceptions (entries 2, 8, 9) relate to the person using the product rather than the use.

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). (Fees apply.)

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 (8)
- Compounded veterinary preparations used by veterinarians (9)
- Oral and topical homeopathic veterinary medicines (10)
- Oral and topical herbal veterinary medicines (11)
- Non-absorbable masking agents used to disguise odours (12)
- Topical non-absorbable and non-solvent cleaning products (13)
- Animal markers (14)
- Over-the-counter first aid preparations (15)
- Topical veterinary medicines (non-medicated) (16)
- Topical hoof preparations (17)
- Non-medicated anti-diarrhoeal veterinary medicines (18)
- Non-medicated orally and rectally administered laxatives and lubricants used on animals (19)
- Non-medicated moist or dry poultice preparations used on animals (20)
- Cauterising preparations used on or applied superficially to animals (21)
- Oral urinary tract modifiers (acidifiers and alkalisers) (22)
- Respiratory tract modifiers (23)
- Agricultural compounds used to extend animal semen or to be used as media for animal sperm, cells, ova, and embryos (24)
- Oral nutritional compounds (pet food, animal feeds) (25)
- Oral gastrointestinal acting microflora-enhancing compounds (OGAME) (26)

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.)

- Spray markers for plants (27)
- Agricultural chemical additives (28)
- Vertebrate or invertebrate repellents applied directly to plants (29)
- Vertebrate or invertebrate attractants applied directly to plants (30)
- Mating disrupters applied directly to plants (31)
- Anti-transpirants for plants (32)
- Frost protectants for plants (33)
- Sunblocks for plants (34)
- Home garden and commercial production of non-food crop plants (35)
- Homeopathic agricultural chemicals used commercially (36)
- Agricultural compounds used in the production of plant tissue cultures (37)
- Agricultural compounds (not containing biologically active ingredients) used to protect plant grafts or plant wounds (38)
- Agricultural compounds (not containing biologically active ingredients) used to provide a physical barrier to infestation or infection of plants (39)
- Agricultural compounds used in the post-harvest treatment of wood-producing crops (40)
- Fertilisers and fertiliser additives (41)

No

Yes

Other authorisation
required

Exempt from registration

5. Plants prohibited in 'herbal preparation' agricultural compounds exempt from registration

The following plants cannot be ingredients in herbal preparations (entry 11) used as veterinary medicines unless the preparation is authorised via registration (section 21 of the ACVM Act), provisional registration (section 27 of the ACVM Act), or approval in special circumstances (section 8C of the ACVM Act).

If your product contains an ingredient derived from any of these plants, your product is not exempt from registration. You should contact the ACVM Group to find out what authorisation is required before you import, manufacture or sell your product.

<p><i>Abrus precatorius</i> seed and root <i>Acorus calamus</i> <i>Amanita</i> (all species) <i>Anadenanthera peregrina</i> <i>Argyreia nervosa</i> <i>Aristolochia</i> (all species) <i>Banisteriopsis caapi</i> <i>Cannabis</i> (all species) <i>Catha edulis</i> <i>Conocybe</i> (all species) <i>Crotalaria</i> (all species) <i>Cynoglossum officinale</i> <i>Erythroxylum coca</i> <i>Haemadictyon</i> (all species) <i>Heliotropium</i> (all species) <i>Ipomoea burmannii</i> (<i>Rivea corymbosa</i>)</p>	<p><i>Ipomoea violacea</i> (<i>Ipomoea tricolor</i>) <i>Lophophora</i> (all species) <i>Opuntia cylindrica</i> <i>Papaver bracteatum</i> <i>Papaver somniferum</i> <i>Peganum harmala</i> <i>Petasites</i> (all species) <i>Piptadenia macrocarpa</i> <i>Piptadenia peregrina</i> <i>Psilocybe</i> (all species) <i>Pteridium aquilinum</i> <i>Sophora secundiflora</i> <i>Strychnos gaultieriana</i> <i>Strychnos ignatii</i> (<i>Ignatia amara</i>) <i>Virola sebifera</i> (for external use)</p>
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6. 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

Veterinary medicines

Some New Zealand trading partners prohibit the use of certain substances in food-producing animals. Consequently, MPI 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).