

# **Regulation under the ACVM Act** ACVM guideline

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# Do I need some kind of ACVM permit to import/manufacture/sell/use Product X in New Zealand?

If Product X meets the definition of an agricultural compound (below), authorisation under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 is required. 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 special 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 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 medicine** means any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal.

# What if I am not sure if Product X is an agricultural compound?

The intended purpose of a product must be to **directly** achieve one of the purposes listed in the definition above. If the intended purpose fits the definition of an agricultural compound, then Product X is considered to be an agricultural compound. If you are not sure about Product X, read <u>Products</u> <u>Regulated under the ACVM Act</u>.

Also, you can request MPI to determine the status of Product X. (There is a fee for this service.)

Class Determination Guideline and Request Form

## Product X is an agricultural compound—what happens next?

All ACVM products require authorisation of some kind.

ACVM products that require individual assessment and approval must be **registered** before they are imported, manufactured for distribution, sold or used in New Zealand. This is to ensure that the products meet certain standards and do not pose unacceptable risks to:

- trade in primary produce
- animal welfare
- agricultural security
- public health.

Registration is also to ensure that the use of products does not breach domestic food residue levels and that sufficient consumer information is provided on the label so the product can be used safely.

Some ACVM products have already been assessed as a group and are considered to be **exempt from registration** if they are used in accordance with conditions specified in the ACVM Regulations. Check the Regulations because the range of exempted products is extensive. You can also check our website or contact us to find out if Product X is exempt, and what conditions are placed on that exemption.

<u>Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances)</u> <u>Regulations 2011</u>

There are other kinds of authorisation as well, such as special circumstances permits. Information is available on our website.

## Product X must be registered—what should I do?

To register Product X:

- gather required information
- lodge an application with MPI.

Information requirements, application forms and guidelines are on our website.

# Can MPI help me through the registration process?

MPI is the regulatory body, so we cannot provide consultation through the registration process. If you are unsure of how to register the product, you should hire a consultant to help you. A list of consultants is on our website. (These consultants, who are not MPI-endorsed at this stage, nominate their own areas of expertise. Refer to the key at the bottom of the list.)

List of consultants

## What if my product information is confidential?

All information submitted to MPI is held subject to an obligation of confidentiality to the supplier of that information. However, registration is a public process and information that is not specified as commercially sensitive/confidential will be public.

Be aware that all information provided to MPI is official information and may be subject to a request made under the Official Information Act 1982. If a request is made under that Act for information you have provided, MPI will consider the request, taking into account its obligations under the Official Information Act 1982 and any other applicable legislation.

For more information read Protection of Confidential Information about ACVM Trade Name Products.

### What if I am not in New Zealand?

Any person can apply to register a product. If you are overseas, you should nominate a New Zealand agent. We require a letter giving authority to the agent who can act on your behalf. (See the application forms and guidelines for details.)

#### Who else should I contact about my product?

If your product is a hazardous substance under the Hazardous Substances and New Organisms (HSNO) Act 1996 or contains new organisms, including genetically modified organisms (GMOs), you need approval from the <u>Environmental Protection Authority</u> (EPA).

For products that contain ingredients of plant or animal origin, you need a Biosecurity Assessment, which is done during the ACVM registration process.

# Contact

For more information, contact us at <a href="mailto:approvals@mpi.govt.nz">approvals@mpi.govt.nz</a>