



FAQ: Regulation under the ACVM Act

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Do I need some kind of 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 ACVM Group of MPI is responsible for authorisation of ACVM products in New Zealand.

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 through the information on our website Overview page. Also, you can request the ACVM Group 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 standards 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.

[Agricultural Compounds and Veterinary Medicines \(Exemptions and Prohibited Substances\) Regulations 2011](#) (External website)

There are other kinds of authorisation as well, such as special circumstances permits and listing as GRAS (generally recognised as safe). Information on these 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 the ACVM Group.

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

Is all this information really necessary?

All information must be provided in an application when it is lodged. However, **before** submitting an application, you may apply to the Group to provide advice on the need for particular information if that information is:

- not relevant to the particular application (you must present a case to explain why the information is not relevant or why some other information would be more appropriate or more relevant), or
- in the public domain (you must provide the information or specify where the information can be readily found), or
- already held by the ACVM Group (if you wish to cross-reference information that is held on some other trade name product [TNP], you must be specific about which TNP and what information is being referenced, and make the connection to your product. If the information being referred to is under data protection, you must obtain a letter of authority from the owner of the data stating that permission is granted to the ACVM Group to consider the information in regard to your application).

Waivers must be provided with an application when it is lodged. For more information, refer to the website document:

Deviation from information specified in the ACVM registration information requirements.

What if my product information is confidential?

All information submitted to the Group 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 the Ministry for Primary Industries 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.

Will my data be protected?

To implement the General Agreement on Tariffs and Trade: Trade-Related Aspects of Intellectual Property Rights (GATT:TRIPS) agreement with respect to data provided in an application to register a product with an innovative active ingredient, the ACVM Act provides legislative protection for confidential supporting information (CSI). If data protection applies, the CSI will not be supplied to anyone outside the Group for any purpose without the “owner’s” approval.

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.)

What are my legal obligations?

The ACVM Group assesses applications in light of the ACVM Act, its Amendments and Regulations when registering a product. As a product registrant, you will have legal obligations under this and other Acts. Other relevant legislation includes:

- Hazardous Substances and New Organisms (HSNO) Act 1996 and its Regulations
- Biosecurity Act 1993
- Fair Trading Act 1986 and the Consumer Guarantees Act 1993
- Health and Safety in Employment Act 1992
- Animal Products Act 1999
- Animal Welfare Act 1999
- Medicines Act 1981 and its Regulations 1984
- Food Act 1981 and its Regulations 1984.

Please note that, under the HSNO Act, an agricultural compound trade name product (TNP) that is a hazardous substance or contains new organisms, including genetically modified organisms (GMOs), cannot be registered unless it has prior substance approval from the Environmental Protection Authority (EPA). (See the application guidelines for details.)

Contact

For more information, contact us at approvals@mpi.govt.nz