

## Class Determination Request Guideline

ACVM guideline (July 2019)

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### 1. Introduction

Please use this guideline to help you complete the [request form](#) for class determination.

If you have any questions, contact us by email: [approvals@mpi.govt.nz](mailto:approvals@mpi.govt.nz)

### 2. Purpose of class determination

The purpose of a class determination is to determine the status of a trade name product under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. Products that fit the definitions in this Act require registration unless they fit one of the categories exempt from registration.

The categories for exemption are listed in Schedule 2 of the [ACVM \(Exemptions and Prohibited Substances\) Regulations 2011](#). Read our guideline [Products regulated under the ACVM Act](#), which explains exemption from the registration process in detail and lists prohibited substances and plants.

If your product requires registration, relevant information and forms are available on our website.

#### Imported products only

If your product does not require registration (as it is either exempt from registration or does not fit the definitions in the Act), your class determination advice letter (or copy) must be presented to Biosecurity New Zealand at the border for the product to be released under the ACVM Act. To avoid delays with clearance and ACVM inspection costs, include a copy of this letter with the declaration information attached to the product.

#### Other requirements

Imported products made from ingredients of biological (plant, animal, or micro-organism) origin must also meet requirements under the Biosecurity Act 1993. See <http://www.mpi.govt.nz/biosecuritynz/> or contact [animal.imports@mpi.govt.nz](mailto:animal.imports@mpi.govt.nz) or [plantimports@mpi.govt.nz](mailto:plantimports@mpi.govt.nz)

Imported products containing a live organism and/or a hazardous substance must also meet requirements under the Hazardous Substances and New Organisms (HSNO) Act 1996. See [www.epa.govt.nz](http://www.epa.govt.nz)

### 3. Timeframe and fees

Each class determination may take up to 15 working days to complete. Applications will not be processed until all information requested on the form is received. If further communication or clarification is required, then additional time and/or charges apply.

The initial determination attracts a fee of \$155.25 (inc GST). If multiple product determinations are made under the one application, the first is charged as above. The other applications are charged on cost versus time, based on \$155.25 (inc GST)/hr. An initial payment of \$155.25 must accompany the application. The remainder will be invoiced if applicable.

On completion of the class determination, you will receive a class determination advice letter informing you of the decision made. You have the right to contest the advice. Send queries electronically to [approvals@mpi.govt.nz](mailto:approvals@mpi.govt.nz). (Note: any additional time taken to answer CD advice queries will be charged at the current hourly rate.)

The advice letter is valid for three years. Any change\* made to the product or any of the other information provided with the application may alter the status of the product. If changes are made, the status of the product can be confirmed if you submit a new application.

\* Change includes any changes to the ingredients, use patterns, claims, statements relating to the way in which the ingredients or product act, or label-referenced website content that differs from the label information on any marketing material or information provided with the product or New Zealand websites controlled by the applicant.

### 4. Request form

#### 1-3 Name and Contact Details

Explained on form.

#### 4A Trade Name Product Details: New Application

Enter the legal trade name of the product.

State active ingredient(s) (that is, the chemical or biological component in a formulated product that is principally responsible for the effect(s) being claimed; distinct from other formulation components such as surfactants, carriers or diluents).

Enter the use claim for the product. State what crop/species the product is intended for and what the product will be used for (for example, supplement for horses to provide a source of nutrients that may be deficient in the diet). **Information on intended use is essential in making a class determination.**

If multiple applications are made together, please group the products by USE.

If applying for more than ten products, please provide product information in an Excel spreadsheet with products grouped by USE.

#### 4B Trade Name Product Details: Renewal Application

Enter the legal trade name of the product and either:

- tick the NO box to confirm that nothing has changed (see \*Change in 3 above) since the previous class determination, or
- tick the YES box and provide details of any information that has changed (see \*Change in 3 above). Highlight changes in the copy of the label provided.

If this information has been previously provided to MPI, confirm that there have been no changes. If not previously provided, include it with the application. A change in the product may require MPI to reassess the existing class determination advice.

As listed in Section 8 of the form, provide a copy of the previous CD advice letter whether or not there have been any changes.

## **5 Websites and Marketing Material (Advertising)**

MPI routinely checks advertising as part of the CD process. Frequently, websites and other material referenced on a product label make claims other than those on the product label. Certain claims or other statements may alter the status of the product under the Act and invalidate class determination advice based solely on label content. (For example, if a therapeutic claim such as “treats arthritis” is made on referenced material for a dietary supplement, the product is a veterinary medicine and is not exempt from registration.)

If the intention is to provide information to the New Zealand market that is different from what is on the product label via written, verbal or electronic media, this information should be provided with the CD request form. If such information is not provided and is later found to be inconsistent with the class determination advice given, your product may be non-compliant with legal requirements.

## **6 For Oral Nutritional Compounds Only**

Complete feeds (not supplements such as vitamin tablets) imported from Australia are subject to the Trans -Tasman Mutual Recognition Agreement (TTMRA). It is accepted that due care has been taken to ensure these products are fit for purpose and no further assessment is required in New Zealand. However, we must have the label to ensure there are no therapeutic claims. Products making therapeutic claims are not subject to the TTMRA.

## **7-8 Requirements**

Explained on application form.

## **9 Applicant Statement**

Explained on application form. Please note that signing the applicant statement is an acknowledgement that you are aware of the continuing obligation to ensure full compliance with all requirements for the exemption status to apply to an ACVM product.

## **10 MPI Service Charge**

Payment may be made by direct credit, credit card or cheque. Please follow the instructions on the application form. Payment should accompany the application. No class determination will be carried out until payment is received.