Ministry for Primary Industries
Manatū Ahu Matua

Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines

ACVM guidance (November 2018)

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1 Background

Agricultural compounds and veterinary medicines are regulated by MPI under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

If your product contains organisms or ingredients of biological origin, you must also apply to MPI for a Biosecurity approval under the Biosecurity Act 1993, or meet the requirements of an import health standard, to be able to import the product into New Zealand.

The importing process

Before you start importing, you need to make sure you're allowed to import the particular product.

Specific guidance for importing Agricultural Chemicals, Veterinary Medicines and Vertebrate Toxic Agents registered under the ACVM Act can be found on the MPI website.

For products that require registration under the ACVM Act, the biosecurity risk assessment can take place either prior to, or at the same time as the ACVM registration process.

To facilitate the application process, MPI has provided a single application form for use for registering a product (or changing the registration of a product), and for requesting a Biosecurity approval.

The application process is managed by ACVM and the risk assessment is conducted by the relevant MPI Biosecurity team.

Upon approval of your product by MPI, imported product will be cleared by MPI Border staff into New Zealand.

The MPI website can help you meet general import requirements.

You can browse a list of import commodities with step-by-step guides here.

Import health standards

Some ACVM products that contain ingredients of biological origin may be covered by an import health standard, and do not require a full biosecurity assessment application. For example, some highly processed plant ingredients are eligible for import under the Import Health Standard for Dried and Preserved Plant Material.

To confirm if your product can be imported under an import health standard and does not require a full biosecurity approval application, send all queries to: animal.imports@mpi.govt.nz You can find out more about import health standards on the MPI website.

You can also search for a specific import health standard on the MPI website.

2 The Biosecurity Approval Application Process

For products that require Biosecurity approval, complete the Biosecurity Summary of Information Provided form, which details all the information required and acts as an index for the information relevant to the risk assessment.

If additional information is required specifically for the risk assessment, and is not relevant to the ACVM registration, this should be identified as Biosecurity Application data and named in accordance with the E Files for ACVM Applications guidelines.

Send all completed forms and information, which must be in English, electronically to approvals@mpi.govt.nz

Biosecurity approval for new products

Use the Registration of an ACVM trade name product (ACVM 1) form for requesting a Biosecurity risk assessment and approval for a new product.

Send us the completed ACVM 1 form, the completed Biosecurity Summary of Information Provided form, and all required supporting documentation (email link above).

If all the information requirements are met, then the assessment will be processed within the timeframe of the ACVM registration process.

The cost of assessment is NZ$117.61 (incl GST) per hour. The fee will be invoiced in conjunction with the ACVM registration charges.

Upon approval, a letter will be issued by the Animal Imports team and sent to you.

Biosecurity approval for most ACVM registered products is valid for the registration period of the product concerned. It is your responsibility as the registrant to advise MPI of any changes to your product that affects the Biosecurity Summary of Information.

If you wish to apply for Biosecurity approval BEFORE submitting your application for ACVM registration, send us the completed Biosecurity Summary of Information Provided form and supporting documentation. If approval is given, a Biosecurity approval for ACVM registration letter will be sent to you. Submit this letter with your ACVM application for registration of a new product.

Biosecurity approval for variations to ACVM registered products

If the variation to ACVM registration also affects the biosecurity risk, advise us by sending the completed Variation to registration of an ACVM trade name product (ACVM 1V) form, an outline of the changes, the completed Biosecurity Summary of Information Provided form and all required supporting documentation.

Examples of changes that may affect the biosecurity risk profile are:

- change in formulation with new ingredients of biological origin
- change in the source or processing of ingredients of biological origin

To enquire whether or not a change affects the biosecurity profile, contact animal.imports@mpi.govt.nz

If all the information requirements are met, then the Biosecurity assessment will be processed as above.

Change in Biosecurity risk profile only

If changes to the product do not require a change to the ACVM registration **but do** affect the biosecurity risk (e.g. change source of a raw ingredient of biological origin), send the completed Biosecurity Summary of Information Provided form and supporting documentation to approvals@mpi.govt.nz. The assessment will be processed with similar timeframes to the ACVM registration process and the fee (as above) will be invoiced by ACVM.

Biosecurity approval for renewals of ACVM registrations

As the expiry period of ACVM registrations and associated biosecurity approvals are aligned, registrants will be asked for information to confirm the biosecurity status of their product at registration renewal. Use the Renewal of registration of an ACVM trade name product (ACVM 1R) form.

Biosecurity approval for provisional registrations

These approvals are to do trial work with a trade name product:

- to obtain more information on that product (for example, about its efficacy, safety, or residue levels) and determine whether it should be registered in New Zealand, or
- to perform general research on the product or trials required for registration of the product in another country.

Use the Provisional registration product data sheet (ACVM 4) form and send us the completed Biosecurity application form, which is appended to ACVM 4, and supporting documentation or provide a copy of your Biosecurity approval letter.

Biosecurity approval for research approvals

These approvals are for the importation and use of unauthorised agricultural compounds for the purpose of research in New Zealand. For authorisation of research work, submit the Research approval application (ACVM 5) form and the completed Biosecurity application form, which is appended to ACVM 5. Also follow the requirements described in Research Approval in New Zealand: ACVM Information Requirements.

Biosecurity approval for products exempt from registration

Some ACVM products are exempt from registration provided the conditions of exemption are met, for example products classed as oral nutritional compounds.

For information regarding whether or not your product is exempt from registration, see Class Determination.

Imported ACVM products with ingredients of biological origin that are exempt from registration under the ACVM Act must meet an import health standard and/or may require an import permit. See https://www.mpi.govt.nz/importing/ for guidance. For further information, contact animal.imports@mpi.govt.nz or plantimports@mpi.govt.nz

Biosecurity approval for special circumstances import approvals

These approvals are for the import and use of an unauthorised agricultural compound, for example importation of:

- an unauthorised veterinary medicine for use by a veterinarian
- an unauthorised agricultural compound for use to fulfil an official export requirement
- an unauthorised agricultural compound for urgent biosecurity use, or
- other circumstances.

Use the Special circumstances import approval request (ACVM 3) form and send us the completed Biosecurity application form, which is appended to ACVM 3, and supporting documentation or provide a copy of your Biosecurity approval letter.

If you have questions about this process for veterinary medicines, agricultural chemicals or vertebrate toxic agents, please contact animal.imports@mpi.govt.nz