

Biosecurity Clearance for Agricultural Compounds and Veterinary Medicines.

A biosecurity clearance is an authorisation given by an inspector at the border allowing a product, such as a veterinary medicine, to enter New Zealand. Before doing so the inspector must be satisfied of certain matters specified in sections 27 and 28 of the Biosecurity Act 1993. The most relevant for veterinary medicines and agricultural compounds is that these products are not risk goods or that they comply with an import health standard.

The Biosecurity Act 1993 defines risk goods:

“Risk goods means any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may—

- (a) cause unwanted harm to natural and physical resources or human health in New Zealand; or
- (b) interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms:”

The border is not a suitable place to make a ‘risk good’ assessment for a veterinary medicine and MAF has a policy that this is undertaken by Import Management within the Animal Biosecurity Group before a product can be registered under the Agricultural Compounds and Veterinary Medicines Act. If the trade name product does qualify then the applicant will be advised in writing and this letter shall be submitted to the ACVM Group as part of the registration process.

A generic import health standard for registered products is being developed and in the meantime the inspector at the border is instructed to give a biosecurity clearance if the product is already registered.

For products that are not registered and ‘generally regarded as safe’ (GRAS) a biosecurity clearance is also required and the applicant shall meet the same information requirements described here for registered products. In this case the importer shall present the letter from the Biosecurity Authority and the class determination from the ACVM Group to the inspector at the border before the product can be released.

A biosecurity clearance is also required for:

- Unregistered medicines accompanying animals,
- Products for which a ‘Declaration for a product not intended for use as an Agricultural Compound.

Information requirements for an assessment

The application form for biosecurity assessment is detailed in Appendix 1: *Application for Biosecurity Clearance of Agricultural Compounds and Veterinary Medicines.*

You will see that the application form is similar to that used by ACVM Group for the registration of veterinary medicines or plant compounds and in some cases the information required is common to both.

Appendix 2 identifies the additional requirements for a vaccine assessment:

Additional Information required for a Biosecurity Clearance of a Veterinary Medicine.

Time for assessment

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

Cost of assessment

At present there is no charge prescribed under the Biosecurity (Costs) Regulations.

If you have questions about this process please contact animalimports@maf.govt.nz.

The application for biosecurity clearance must be made to:

**Animal Imports
MAF Biosecurity New Zealand
PO Box 2526
WELLINGTON**

Application for Biosecurity Clearance of Agricultural Compounds and Veterinary Medicines.

Complete this application for products that you propose to import. The information is required by the Biosecurity Authority to undertake a risk assessment for biosecurity clearance. Many of the questions are common to the application form used by the Agricultural and Chemical Veterinary Medicine Group for the registration of veterinary medicines. These requirements can be found on the web-site:

<http://www.maf.govt.nz/acvm/publications/information-requirements/regvm.pdf?>

1 Trade name of the veterinary medicine/plant compound

2 Registration number (if assigned)

3 Registrant details

Name:

Postal address:

Street address (if different from above):

Tel:

Fax:

E-mail:

Contact name:

4 NZ agent (complete if different from above)

Name:

Postal address:

Street address (if different from above):

Tel:

Fax:

E-mail:

5 General use claim

6 Manufacturer(s) of the formulated product (complete for each manufacturer)

Company name:

Address:

7 Active ingredient(s) and concentration (in g/L or g/kg)

8 Registration type

See Registration Requirements for Veterinary Medicines in New Zealand.

9 Product type

Select a product type from Attachment 2,

See Registration Requirements for Veterinary Medicines in New Zealand.

10 Administration method

Select an administration method from Attachment 3,
See *Registration Requirements for Veterinary Medicines in New Zealand*.

11 Formulation type

Select a formulation type from Attachment 4,
See *Registration Requirements for Veterinary Medicines in New Zealand*.

12 Use of veterinary medicine

Delete those that do not apply. Please state species. See Glossary in *Registration Requirements for Veterinary Medicines in New Zealand* for the definitions.

- Companion animal
- Food producing animal
- Vertebrate pest control
- Other

13 Outline of use

Include host(s) and target organism(s).

14 Does the product contain a viable new organism or a genetically modified organism? Y/N

If 'yes' include a copy of the relevant ERMA approval.

15 Formulation details

Provide details of the full composition of the final formulated trade name product in the table below:

Ingredient name: Enter the accepted ISO common name or IUPAC name for the active ingredient or, where this has not been established, provide the chemical name. **If trade name products are used as an ingredient, please provide full formulations** of all trade name products used, or arrange to have complete formulations sent directly to Import Management by the supplier.

Quantity: The concentration of all ingredients must be provided.

- Chemical-based formulations are to be expressed in **g/litre for liquids** and **g/kg for solids**.
- Biological-based formulations are to be expressed in appropriate international units ensuring consistency.

Function: Describe the purpose for each of the ingredients e.g. active ingredient, emulsifier, surfactant, filler etc. Definitions can be found in the Glossary, *Registration Requirements for Veterinary Medicines in New Zealand*. **Do not** use 'inert'.

16 Is your product a vaccine?

If yes, complete the information requirements outlined in Appendix 2 and skip question 17.

17 If your product is not a vaccine but contains ingredients of plant or animal origin

For products containing organisms provide:

- systematic name and strain of the bacteria, protozoa, fungi, rickettsia, nematode or virus and the taxonomic description of the agent, serotype, strain or mutant;
- common name or alternative and superceded names;
- composition of the unformulated material, microbiological purity, nature and identity of any culture media, impurities and content of extraneous organisms.

For processed products provide:

Origin of the ingredient(s) of plant and animal origin

Complete for each ingredient (raw material) and for each manufacturer if more than one manufacturer:

Identify the raw materials used, the species and country of origin. Include health certification referring to disease country freedom and herd or flock of origin disease testing.

Describe the manufacturing processes for preparing the product.

Briefly outline the processes designed to render the product(s) sterile (e.g. heat treatment, filtration, acid or alkali treatment, irradiation, long term maturation etc). Include relevant parameters (e.g. temperature, pH level, radiation dose) and the time the product is maintained at these levels.

Each major step in the production process should be shown in a flow-chart diagram. Each step on the flow-chart should be cross-referenced to the application, which should contain details of the materials used and results of any tests conducted.

Describe the operational environment, quality systems and controls used for manufacturing. The manufacturer's GMP may include SOPs and/or specifications of the approved source, sterilisation procedure (if applicable) and pathogen testing applied to each product.

Expert opinion

If available, the applicant shall provide an opinion on the likelihood of the product containing associated organisms from an independent expert authority who is familiar with the manufacturing process. Include the following information:

Name:

Postal address:

Street address (if different from above):

Tel:

Fax:

E-mail:

18 Overseas regulatory status

List the countries where the product is already registered.

19 Confidential information

Where information is confidential, please ensure that you have contacted the manufacturer/supplier to arrange for information to be supplied to us directly.

20 Checklist

Applications **must** always contain:

- Covering letter
- Information requirements of this form
- Clear identification of confidential supporting and/or commercially sensitive information.

Send information to

The agency collecting and holding this information is:

Animal Imports
MAF Biosecurity New Zealand
PO Box 2526
WELLINGTON

Inquiries

If you have questions about this process please contact animalimports@maf.govt.nz.

Information collected

You have the right of access to, and correction of, personal information supplied in this form as provided by the information privacy principles in section 6 of the Privacy Act 1993.

All information provided is subject to the Official Information Act 1982. Specific protection is provided to Confidential Supporting Information under sections 73, 74, 109 and 121 of the ACVM Act 1997.

Declaration

I declare that all information that I have provided in this application for biosecurity clearance is true and correct.

Signature: _____

Name: _____

Date: _____

Appendix 2

Additional Information required for a Biosecurity Clearance of a Veterinary Vaccine

Information identified below is additional to that required in “Application for Biosecurity Clearance of Veterinary Medicines and Agricultural Compounds”

Information should be presented in a format consistent with these requirements or as a summary document cross-referenced to registration dossiers and or drug master files which should also be submitted.

1 Registration and approvals

The applicant shall submit all relevant approvals of the production facility, registrations and approvals of the product by the country of manufacture and other importing countries. Copies of any relevant current import and or export permits should also be provided.

Details of doses used commercially in other countries for each target species should be provided in support of the application.

2 Flow-chart of production process

Each major step in the production process should be shown in a flow-chart diagram. Each step on the flow-chart should be cross-referenced to the application, which should contain details of the materials used and results of tests conducted.

3 Testing standards

MAF will normally accept procedures to test for pathogens that are specified in the Code of Federal Regulations (9CFR 113) or other standards. Details of all testing protocols should be submitted with the application.

4 Standard operation procedure (SOP)

The manufacturer’s GMP must include SOPs and/or specifications of the approved source, sterilisation procedure (if applicable) and pathogen testing applied to each product.

The applicant must provide copies of test results and SOPs relevant to this analysis. Test results must be able to demonstrate compliance with the relevant SOP.

5 Materials of biological origin

The applicant must provide detailed information on all components of biological origin used directly or indirectly in production of the vaccine. Such components include viral/bacterial seeds, cell lines, trypsin, nutritive factors (e.g. serum), fermentation broths/culture media and excipients. Every ingredient of animal origin contained in or used in the production of the component must also be listed and the country and species of origin, approximate date of collection, processing/treatment and testing specified.

6 Certification and audit trails

Information shall be provided to show that an audit trail can track the country, species and date of origin of each product of animal origin used in production of the vaccine.

Such audits should be able to correlate batches of finished product with all raw ingredients.

7 Other pathogens held and vaccines produced at the facility

All pathogens held and vaccines produced within the vaccine manufacturing facility must be listed. Details must be provided of other activities on the same site (e.g. vaccine research involving challenge trials, veterinary pathology and diagnostic services, etc) and on neighbouring sites (e.g. intensive livestock production, abattoirs, animal research facilities etc.).

8 Sterilisation of components of animal origin

Sterilisation procedures must be validated and a copy of the appropriate SOP submitted with the application.

9 Adverse reaction reporting

A summary of reported adverse reactions and subsequent investigations should be submitted. The total number of doses sold should support this. These records may be used as a possible indicator of contamination with, or freedom from, extraneous agents.

10 Master seed virus

A well-documented history of the master seed must be made available. The origin, date of isolation, passage history, reversion to virulence, purity and identity confirmation studies must be provided. Details of cell lines and nutritive media used for the transport, storage and propagation of the master seed virus should also be provided.

For master seed virus created many years ago, detailed information on the initial nutritive factors used may not be available. In this situation, it may be possible in some circumstances to establish the safety of the master seed virus by additional testing and a history of safe use over many years in live vaccines. Frequent use and extensive pathogen testing over many years in research laboratories and inactivated vaccine manufacture may also provide an additional level of biosecurity confidence.

Details must be provided of the testing methods used to establish freedom from contamination by bacteria, fungi, mycoplasma, viruses and pathogens.

11 Working and production seed viruses

Describe the tests used to identify potential pathogens in working and production viruses.

12 Master and working cell seeds

A well documented history of the master cell seed must be available. The country, species, date of creation and number of passages of the master cell seed since its creation must be specified. Identity and karyological studies must have been undertaken. The country and species of origin of each nutritive factor used since its creation should also be specified.

For cell lines created many years ago, detailed information on the initial nutritive factors used may not be available. In this situation, it may be possible in some circumstances to establish the safety of the cell line by additional testing and a history of safe use over many years in live vaccines. Frequent use and extensive pathogen testing over many years in research laboratories and inactivated vaccine manufacture may also provide an additional level of biosecurity confidence.

Details must be provided of the testing methods used to establish freedom from contamination by bacteria, fungi, mycoplasma and viruses.

13 Master seed bacteria

A well documented history of the master seed must be made available. The species, origin, date of isolation, passage history and purity and identity confirmation studies must be provided. Information shall be presented which supports the biosecurity safety of the master seed. Details of culture media used for transport, storage and propagation of the bacteria should also be provided.

For master seed bacteria created many years ago, detailed information on the initial nutritive factors used may not be available. In this situation, it may be possible in some circumstances to establish the safety of the master seed by additional testing and a history of safe use over many years in live vaccines. Frequent use and extensive pathogen testing over many years in research laboratories and inactivated vaccine manufacture may also provide an additional level of biosecurity confidence.

All master seed bacteria must be tested for identity and purity such that the master seed is shown to contain only the species and strain of bacteria stated.

Details must be provided of the testing methods used to establish freedom from contamination of bacteria, fungi, mycoplasma and viruses and pathogens.

14 Working and production bacteria

Describe the tests used to identify potential pathogens in working and production bacteria.

15 Nutritive factors

Nutritive factors include serum, foetal serum, serum albumins and other serum products used for cell line maintenance and growth. They may also be used for the growth of leptospira and certain other organisms. The country and species of origin, processing and any pathogen testing must be detailed with the application.

Appropriate government health certification and other documentation providing an audit trail from country of origin to final vaccine must be provided.

Government certification of origin shall be provided for all animal serum and serum products used in production.

Describe the tests used on serum and other nutritive factors for bacterial and fungal contamination, mycoplasmas, viruses and specific pathogens.

16 Trypsin and other enzymes of animal origin

Provide details on the country of origin, species of origin, processing and any pathogen testing. Appropriate government health certification and other documentation providing an audit trail must be provided.

Evidence shall be provided to show that the country of origin is free of the major OIE List A pathogens relevant for the species of origin unless the product is shown to be effectively sterilised prior to use.

17 Fermentation broths and culture media

All ingredients used in the fermentation broth/production culture media must be listed in the import application.

Country and species of origin of each ingredient of animal origin must be specified along with details of any processing, treatments or testing of either the ingredients or the final culture media/fermentation broth.

Unless meat extracts are effectively sterilised before use, information shall be provided to show that the countries of origin are free of the major diseases on the OIE List A.

Identify the tests used for detecting bacterial and fungal contamination, mycoplasmas, extraneous pathogens, pathogens which are pathogenic to the species of origin of any fermentation/culture ingredients of animal origin.

18 Final product testing - viral and bacterial vaccines

Describe the testing used on batches of live final bulk vaccines.