

**Biosecurity Approval of Imported Agricultural Compounds or Veterinary Medicines**

**Summary of Information Provided Form (July 2021)**

This information is required by the Biosecurity Act 1993 to undertake a risk assessment for biosecurity approval.

Time for assessment: If all the information requirements are met, the assessment will be processed within the time frame of the ACVM registration process.

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

If you have questions about this process please contact [animal.imports@mpi.govt.nz](mailto:animal.imports@mpi.govt.nz)

Send this form and attachments for products that you propose to import to ACVM at [approvals@mpi.govt.nz](mailto:approvals@mpi.govt.nz) with your ACVM product registration application. Please send electronic files.

Biosecurity approval for most ACVM registered products is valid for the registration period of the product.

If there are changes that affect the product’s biosecurity status, **send an outline of the changes, this form and supporting information to** ACVM at [approvals@mpi.govt.nz](mailto:approvals@mpi.govt.nz)

Refer to the Privacy Act 2020 and Official Information Act 1982 notices at the end of this form regarding collection of

information by the Ministry for Primary Industries.

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| Identity | | |
| **1.1** | **Applicant** |  |
| **1.2** | **Trade name** |  |
| **1.3** | **Registration number (if known)** |  |

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| Information Requirements Identify information by referencing data supplied in support of your ACVM product registration or variation application, or provide as attachments. Where you are supplying information to support a change to an existing Biosecurity approval, you only need to complete the relevant sections.  When referencing data supplied, reference the electronic file name and page numbers. | | |
| **2.1** | Information required for ALL products | File Reference or Attachment Number |
| **A** | **List ingredient(s) originating from an organism (e.g. from a plant, animal, parasite, fungus, bacteria, or virus).**  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, if applicable. |  |
| **B** | **Formulation details**  Provide details of the full composition of the final formulated product. |  |
| **C** | **Manufacturing processes for preparing the product**  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.  Provide a flow chart diagram showing each major step in the production process. Cross-reference each step to 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. |  |
| **D** | **Expert opinion**  If available, 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:  Email: |  |

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| **2.2** | Additional information required for products containing live organisms that are not veterinary vaccines | File Reference or Attachment Number |
| **A** | Systematic name and strain of the bacteria, protozoa, fungi, rickettsia, nematode or virus and the taxonomic description of the agent, serotype, strain or mutant |  |
| **B** | Common name or alternative and superseded names |  |
| **C** | Microbiological purity |  |
| **D** | Nature and identity of any culture media |  |
| **E** | Impurities |  |
| **F** | Confirmation/evidence of freedom from extraneous organisms. If extraneous organisms are present, confirm identity and quantity. |  |

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| **2.3** | Additional information required for products that are  veterinary vaccines | File Reference or Attachment Number |
| **A** | **Materials of biological origin**  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.  List every ingredient of animal origin contained in or used in the production of the product, the country and species of origin, approximate date of collection if available, processing/treatment and testing specified. |  |
| **B** | **Testing standards**  MPI will normally accept procedures to test for pathogens that are specified in the Code of Federal Regulations (9CFR 113) or other standards.  Submit details of all testing protocols with the application. |  |
| **C** | **Certification and audit trails**  Provide information 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. |  |
| **D** | **Other pathogens held and vaccines produced at the facility**  List of all pathogens held and vaccines produced within the vaccine manufacturing facility.  List of other activities on the same site (e.g. vaccine research involving challenge trials, veterinary pathology and diagnostic services) and on neighbouring sites (e.g. intensive livestock production, abattoirs, animal research facilities). |  |
| **E** | **Sterilisation of components of animal origin**  Sterilisation procedures must be validated.  Submit a copy of the appropriate SOP with the application. |  |
| **F** | **Master seeds (virus, bacteria and cells)**  A well-documented history of the master seed must be made available.  Provide the origin, date of isolation, passage history, reversion to virulence, purity and identity confirmation studies.  Provide details of cell lines and nutritive media used for the transport, storage and propagation of the master seed.  For master seeds 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.  Provide details of the testing methods used to establish freedom from contamination by bacteria, fungi, mycoplasma, viruses and pathogens. |  |
| **G** | **Working and production seeds (virus, bacteria and cells)**  Describe the tests used to identify potential pathogens in working and production seeds. |  |
| **H** | **Nutritive factors**  Nutritive factors include serum, foetal serum, serum albumin and other serum products.  Detail the country and species of origin, processing and/or any pathogen testing. |  |
| **I** | **Trypsin and other enzymes of animal origin**  Provide details on the country of origin, species of origin, processing and any pathogen testing. |  |
| **J** | **Fermentation broths and culture media**  List all ingredients used in the fermentation broth/production culture media in the import application.  Specify country and species of origin of each ingredient of biological origin along with details of any processing, treatments or testing of either the ingredients or the final culture media/fermentation broth. |  |
| **K** | **Final product testing – live vaccines**  Describe the testing used on live vaccines. |  |

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

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| Checklist |
| Applications must always contain:  1. Completed ACVM application form:   * *Registration of an ACVM trade name product (ACVM 1)* * *OR Variation to registration of an ACVM trade name product (ACVM 1V)* * *OR Renewal of registration of an ACVM trade name product (ACVM 1R)*   2. Information required on this form  3. Clear identification of confidential supporting and/or commercially sensitive information |

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| **5. Applicant Statement** | | | |
| I confirm that the information supplied in and with this application for Biosecurity approval is truthful and accurate to the best of my knowledge. | | | |
| **Name** |  | **Tel** |  |
| **Title** |  | | |
| **Signature** |  | **Email** |  |
| **Date** |  |

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| **Collection of Information** |
| **Collection of Personal Information**  Pursuant to Principle 3 of the Privacy Act 2020, we advise that:   * This information is being collected for the purpose of registering an agricultural compound as a trade name product under the Agricultural Compounds and Veterinary Medicines Act 1997; and * The recipient of this information, which is the agency that will collect and hold the information, is the Ministry for Primary Industries, PO Box 2526, Wellington 6140; and * Some of the information being collected in Part A will be displayed on a public register; and * The collection of information is authorised under section 10 of the ACVM Act; and * The provision of this information is necessary in order to process this application for registration; and * The supply of this information is voluntary; and * Failure to provide the requested information is likely to result in a return of the application form to the applicant, and in accordance with the ACVM Act, may ultimately result in a refusal to register the product; and * Under Principles 6 and 7 of the Privacy Act 2020, you have the right of access to, and correction of, any personal information which you have provided.   **Collection of Official Information**  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 in this declaration, the Ministry for Primary Industries will consider any such request, taking into account its obligations under the Official Information Act 1982 and any other applicable legislation. |