**Production questionnaire: Viral vectors**

**Form authorised for the request of information under the *Biosecurity* *Act 2015***

* 1. **Section A: General information**

|  |  |
| --- | --- |
| **Purpose of this form** | To support an [import permit application](https://www.agriculture.gov.au/import/online-services/bicon) by an Australian entity or individual to import viral vectors into Australia. |
| **Who should complete this form** | Review the scenarios below to determine who must complete this form:

|  |  |
| --- | --- |
| * Goods **have not** undergone any manufacturing/processing (e.g., animal tissue samples) and sourced from specific supplier/s
 | This form must be completed by the supplier of the goods. This must be an individual or authorised representative of a company who sampled/collected the goods intended for import into Australian territory and can attest to the health of the source animals if required. |
| * Goods **have not** undergone any manufacturing/processing (e.g., animal tissue samples) and/or **not sourced from specific supplier/s** i.e., sourcing of goods needs to be flexible.
 | This form can be completed by the importer of the goods. Note that resulting import conditions may be more restrictive and/or more detailed consignment-specific evidence may be required to evidence the goods meet import conditions.  |
| * Goods **have** undergone manufacturing/processing into a fully finished product i.e., with a brand/product name or code (e.g., antisera)
 | An authorised representative of the **physical manufacturer\*** of the goods must complete this form. \*The department defines a physical manufacturer’ as the facility where the products are manufactured. This includes buildings and areas where the products are stored or processed and any other buildings or areas within the boundary of the site.OR |
| * Goods **have** undergone manufacturing/processing into a fully finished product i.e., with a brand/product name or code (e.g., antisera) continued…
 | If the form cannot be completed by an employee of the physical manufacturing site, the form can be completed by an authorised representative of the **legal manufacturer.** The signee must provide sufficient documentation in relation to:* the manufacturing of the goods,
* the locations of the physical manufacturing sites and head office
* evidence that the entity signing/supplying the manufacturers declaration has adequate oversight of the manufacturing process and would have the capacity to notify the department should any change, in the sourcing or manufacturing process of the products, occur.

This evidence may include standard operating procedures (SOPs) and/or evidence of oversight/control of manufacturing processes and sourcing of ingredients. This evidence must be supplied in addition to, and accompanying, this production questionnaire. |

 |
| **To complete this form** | Answer all questions truthfully and accurately. Failure to complete questions or provide supporting documentation will result in delays in the processing of the import permit application.**Electronically**Download the document to your computer and save any changes.**Manually**Use black or blue penPrint in BLOCK LETTERSMark boxes with a tick þ or a cross ýAttach additional sheets if space is insufficient |
| **You must submit these documents with this form** | [ ]  A copy of any application that has been submitted to and approved (or considered an exempt dealing) by the Office of the Gene Technology Regulator (OGTR) or an Institutional Biosafety committee (IBC) for the use of the recombinant viral vector (if applicable)**Any additional documents must be:** * on the manufacturer’s letterhead (including company address and country).
* signed by a senior company employee from the site of manufacture (or legal manufacturer with evidence supplied), whose name, title and contact details also appear.
* dated within the last 6 months, free from erasures and uncertified alterations (all alterations must be initialled by the senior company employee responsible for signing the declaration).

All documentation supplied in support of an import permit application is required to meet the department’s [minimum documentary and import declaration requirements policy](https://www.agriculture.gov.au/import/arrival/clearance-inspection/documentary-requirements/minimum-document-requirements-policy). |
| **To submit this form** | **Option 1 (preferred)**Submit your completed, signed questionnaire and all additional documents and attachments to the Australian importer for inclusion in their import permit application.**Option 2 Questionnaires containing commercial-in-confidence information**All commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law.Post or email (preferred) the completed questionnaire and all additional documents and attachments (referencing the import permit application number and marked ‘commercial-in-confidence’ where relevant) to:Biosecurity Import Services TeamDepartment of Agriculture, Fisheries and Forestry GPO Box 858Canberra ACT 2601Email Imports@agriculture.gov.au |
| **More information** | Phone 1800 900 090 (within Australia)+61 3 8318 6700 (outside Australia)Email Imports@agriculture.gov.au |

## Section B: Contact details

1. **Details of authorised representative completing this form**

|  |  |
| --- | --- |
| **Legal entity name** |  |
| **Authorised person to sign this form *(must be an employee of the facility)*** | **Full name:**  | **Position in company/Job title:** |
| **Select applicable option** | [ ]  Physical manufacturer [ ]  Legal manufacturer[ ]  Supplier [ ]  Importer [ ]  Other (provide details):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Address** |  |
| **Phone (include area code):**  |  | **Fax:** |  |
| **Email:** |  |

1. **Facility where products are manufactured (if the same as question 1, write ‘As above’). Include multiple facilities if required.**

|  |  |
| --- | --- |
| **Name of manufacturer (legal entity name)** |  |
| **Address** |  |
| **Phone (include area code):**  |  | **Fax:** |  |
| **Email:** |  |

1. **Exporter’s details (if exporter and manufacturer details are the same, write ‘As above’)**

|  |  |
| --- | --- |
| **Name of manufacturer (legal entity name)** |  |
| **Authorised person to sign this form *(must be an employee of the facility)*** | **Full name:**  | **Position in company/Job title:** |
| **Address** |  |
| **Phone (include area code):**  |  | **Fax:** |  |
| **Email:** |  |

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## Section C: Product to be exported to Australia

**If you are exporting multiple products, provide a separate version of this section for each product.**

1. **What is the scientific name of the original vector virus? i.e. the virus before it was genetically modified with deletion and insertion of genes.**

Identify the virus to at least the level of species.

### **What is the name of the vector/s that will be imported?**

1. **Does the viral vector contain the whole genome or a whole autonomous genomic region\* of any organism other than sequences derived from or homologous to sequences from:**
2. Multicellular organisms (excluding fungi and prions), and/or
3. Standard laboratory microorganisms and infectious agents (Appendix 1), and/or
4. Listed Department of Agriculture, Fisheries and Forestry approved starter cultures (Appendix 2)?

*\*Autonomous genomic regions are distinct nucleic acid sequences which can be replicated independently such as transposons, entire viral genomes, entire segments of a segmented viral genome, and natural plasmids#.*

*# A natural plasmid is a plasmid which naturally occurs in a bacterium, protozoan or a multicellular organism that has not been manipulated or genetically engineered.*

[ ]  Yes - please provide details below on what sequences the vector contains. Microorganisms and infectious agents should be identified to at least the level of species.

[ ]  No – go to question 7.

1. **Is the vector designed to increase any of the following traits in the organisms they are transduced, transformed, or introduced into (other than antibiotic resistance genes used to facilitate selection of the vector):**
2. Pathogenicity
3. Virulence
4. Ability to replicate and invade host cells
5. Host range and/or susceptibility
6. Increase mode of transmission to animals
7. Ability to evade the host immune system
8. Increased cytotoxic or oncogenic effects?

[ ]  Yes - please provide details below.

[ ]  No – go to question 8.

1. **Is the viral vector replication-competent or replication-defective?**

[ ]  Yes - please provide details below.

[ ]  No – go to question 9.

1. **In what form is the recombinant viral vector be exported to Australia? E.g., as viral particles, within cloning and expression vectors contained in a chemical buffer, in a microorganism culture, etc.**

1. **If the viral vector is exported to Australia in the form of cloning and expression vectors, do the cloning and expression vectors meet all the following criteria?**
2. The cloning and expression vectors are plasmids, cosmids, yeast artificial chromosomes or bacterial artificial chromosomes only; and
3. The vectors are deliberately constructed for a specific purpose such as cloning and expression or production of viral vectors; and
4. In the case of plasmids or cosmids, they are non-integrative and non-conjugative; and
5. Does not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions.
6. Does not contain nucleic acid derived from and/or associated with, or homologous to the following:
7. [Pathogens of animal biosecurity concern for biological products](https://www.agriculture.gov.au/biosecurity-trade/policy/legislation/pathogens-of-biosecurity-concern#pathogens-of-highest-animal-biosecurity-concern) (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
8. [Disease agents causing Listed Human Diseases](https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-biosec-list-diseases.htm) as published on the Department of Health's website and listed under the Biosecurity (Listed Human Diseases) Determination 2016.
9. Monkeypox virus (Mpox)
10. Polio virus
11. Prion proteins (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species.

[ ]  Yes - go to question 11.

[ ]  No - please provide details below about how they do not meet the listed criteria.

1. **Please provide any additional relevant information that will assist with understanding the nature of the viral vector. This should include information on stability of the construct, any known unexpected outcomes or adverse effects associated with use of the vector in animals or humans.**

**Section D: Declaration**

**This section is to be completed by the signee named in** [**section B**](#_Section_B:_Contact) **of this form.**

It is a criminal offence under Division 136 of the *Criminal Code Act 1995* to knowingly give false or misleading information to a Commonwealth officer exercising powers under Commonwealth law. This offence carries a potential penalty of 12 months’ imprisonment.

I declare that the information in this form is true and accurate to the best of my knowledge. I understand that giving false or misleading information is a serious offence.

If I become aware that the information I have provided is incomplete or incorrect, I will notify the Department of Agriculture, Fisheries and Forestry as soon as practicable.

If the department issues an import permit for products referred to in this form, I declare that the products exported to Australia will comply with all conditions on that import permit.

If manufacturing processes change so that products are no longer compliant with all conditions on the import permit, I will provide details of the change to the Australian importer so that a new application for an import permit (or an application to amend the current import permit) can be submitted to the department.

I have read and understood the privacy notice and [Privacy Policy](https://www.awe.gov.au/about/commitment/privacy) and the commercial-in-confidence notice.

**Signature (type or sign your name)**

**Full name**

**Date (dd/mm/yyyy)**

**Section E: Privacy notice**

Personal information means any information or opinion about an identified, or reasonably identifiable, individual. Personal information that is collected under or in accordance with the *Biosecurity Act 2015* is also ‘protected information’ under the Biosecurity Act.

The Department of Agriculture, Fisheries and Forestry is authorised under the Biosecurity Act to collect your personal information for the purposes of determining import conditions for your veterinary therapeutic products and for other related purposes. If you fail to provide some or all of the relevant personal information requested in this form, the department may be unable to process the import permit application that relates to this form.

Information collected by the department will only be used or disclosed under the Biosecurity Act. The department may disclose your personal information to the Department of Health and Aged Care and the Department of Climate Change, Energy, the Environment and Water, and other Australian Government agencies, persons or organisations where necessary for these purpose. It will not usually be disclosed overseas. It will only be disclosed if authorised under the Biosecurity Act.

See our [Privacy Policy](https://www.awe.gov.au/about/commitment/privacy) to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933 (or +61 3 8318 6700 outside Australia).

**Section F: Commercial-in-confidence notice**

Commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law.

**Section G: Appendices 1 and 2**

**Appendix 1: List: Standard laboratory microorganisms and infectious agents**

The following list contains microorganism and infectious agent that do not require biosecurity containment. These microorganisms are endemic (occur in Australia) and are commonly imported by laboratories in Australia.

|  |  |  |  |
| --- | --- | --- | --- |
| *Achromobacter spp.* | *Acidianus spp.* | *Acidiphilium spp.* | *Acidithiobacillus spp.* |
| *Acremonium cellulolyticus* | *Actinomadura malachitica* | *Actinomadura viridis* | *Actinomyces rectiverticillatus* |
| *Adeno-associated virus*  | *Aeromonas hydrophila* | *Alcaligenes denitrificans* | *Alicyclobacillus spp.* |
| *Ampelomyces quisqualis* | *Anabaena cylindrica* | *Anaerobacter polyendosporus* | *Aneurinibacillus migulanus (formerly Bacillus migulanus)* |
| *Aquifex spp.* | *Arthrobacter picolinophilus* | *Arthrobacter spp.* | *Aspergillus spp.* |
| *Azorhizobium caulinodans* | *Azotobacter spp.* | *Bacillus aminoglucosidicus* | *Bacillus atrophaeus (formerly Bacillus subtilis var. niger)* |
| *Bacillus brevis syn. Brevibacillus brevis* | *Bacillus cereus excluding Biovar anthracis* | *Bacillus fluorescens putidus* | *Bacillus geniculatus* |
| *Bacillus ginsengihumi* | *Bacillus licheniformis* | *Bacillus megaterium (excluding pv. cerealis)* | *Bacillus mesentericus* |
| *Bacillus methylotrophicus* | *Bacillus mojavensis* | *Bacillus pasteurii* | *Bacillus pumilus syn. Bacillus mesentericus, Bacillus aminoglucosidicus* |
| *Bacillus putidus* | *Bacillus simplex* | *Bacillus sphaericus* | *Bacillus stearothermophilus* |
| *Bacillus subtilis* | *Bacillus thuringiensis* | *Bacteroides spp.* | *Bartonella spp.* |
| *Beauveria bassiana* | *Bordetella spp.* | *Botryococcus spp.* | *Brachyspira spp.* |
| *Brevibacillus spp. (excluding B. laterosporus)* | *Burkholderia pseudomallei* | *Campylobacter spp.* | *Caulobacter spp.* |
| *Chlamydia trachomatis* | *Chlamydophila pneumonia* | *Chlorella spp.* | *Chryseobacterium spp. (excluding C. scophthalmum)* |
| *Cicinnobolus cesatti* | *Citrobacter spp.* | *Clostridium spp.* | *Comamonas acidovorans* |
| *Corynebacterium spp. (excluding C. pseudotuberculosis)* | *Cronobacter spp.* | *Cryptococcus spp.* | *Cryptomonas spp.* |
| *Cryptosporidium spp.* | *Dehalobacter spp.* | *Dehalococcoides spp.* | *Dehalogenimonas spp.* |
| *Delftia acidovorans* | *Desulfobacter spp.* | *Desulfovibrio spp.* | *Ensifer adhaerens* |
| *Ensifer meliloti* | *Entamoeba spp.* | *Enterobacter asburiae* | *Enterobacter spp.* |
| *Enterococcus spp.* | *Enterovirus (human origin only, and excluding swine vesicular disease virus and human enterovirus C)* | *Entomophthora anisopliae* | *Erwinia tasmaniensis* |
| *Escherichia spp.* | *Ferroplasma spp.* | *Fusarium venenatum* | *Geobacillus spp.* |
| *Geobacter spp.* | *Giardia spp.* | *Gigaspora margarita* | *Gliocadium catenalatum* |
| *Haemophilus spp.* | *Human Adenovirus Types 1-51* | *Human coxsackieviruses 1-24* | *Human echovirus 1-33* |
| *Human hepatitis virus A, B, C, D, E, G &TTV* | *Human Herpes virus 1-8 (includes Herpes simplex virus 1 and 2, Varicella zoster, Epstein-Barr virus and Cytomegalovirus)* | *Human immunodeficiency virus (HIV)* | *Human noroviruses* |
| *Human papilloma virus* | *Human respiratory syncytial virus* | *Human rhinovirus* | *Isochrysis galbana* |
| *Klebsiella spp.* | *Legionella spp.* | *Leptospira copenhageni (Leptospira interrogans serovar Copenhageni)* | *Leptospira gripptotyphosa (Leptospira interrogans serovar Gripptotyphosa)* |
| *Leptospira hardjobovis (Leptospira borgpetersenii serovar hardjo-bovis)* | *Leptospira icterohaemorrhagiae (Leptospira interrogans serovar Icterohaemorrhagiae)* | *Leptospira pomona (Leptospira interrogans serovar Pomona)* | *Leptospirillum spp.* |
| *Listeria spp.* | *Magnetospirillum spp.**(formerly Aquaspirillum spp.)* | *Metapneumovirus (human)* | *Metarhizium acridum* |
| *Metarhizium anisopliae var. anisopliae* | *Methanococcus spp.* | *Microtetraspora viridis* | *Moraxella spp. (includes subgen. Branhamella and subgen. Moraxella) (excluding M. anatipestifer)* |
| *Morganella spp.* | *Murine cytomegalovirus (MCMV)* | *Murine leukaemia virus* | *Mycobacterium spp. (excluding M. bovis and M. caprae)* |
| *Mycoplasma pneumoniae* | *Nannochloropsis spp.* | *Neisseria spp.* | *Nippostrongylus brasiliensis* |
| *Nocardia calcarea* | *Ochrobactrum anthropi* | *Paenarthrobacter spp.* | *Paenibacillus alvei* |
| *Paenibacillus brasiliensis* | *Parainfluenza virus (human)* | *Pediococcus spp.* | *Penicillium chrysogenum* |
| *Penicillium oxalicum* | *Penicillium velutinum* | *Pleomorphomonas oryzae* | *Porphyromonas spp.* |
| *Pristionchus americanus* | *Pristionchus maupasi* | *Pristionchus pacificus* | *Proteus spp.* |
| *Providencia spp.* | *Pseudomonas acidovorans* | *Pseudomonas aeruginosa* | *Pseudomonas antarctica* |
| *Pseudomonas citronellolis* | *Pseudomonas convexa* | *Pseudomonas eisenbergii* | *Pseudomonas fluorescens (excluding biovar II)* |
| *Pseudomonas geniculata* | *Pseudomonas incognita* | *Pseudomonas monteilii* | *Pseudomonas ovalis* |
| *Pseudomonas putida* | *Pseudomonas rugosa* | *Pseudomonas striata* | *Rhabditis myriophila* |
| *Rhizobium meliloti* | *Rhodobacter spp.* | *Rhodococcus spp.* | *Roseomonas spp.* |
| *Rubella virus* | *Rubrivivax spp.* | *Saccharopolyspora spinosa* | *Saccharopolyspora spp.* |
| *Salmonella Adelaide (Salmonella enterica subsp. enterica serovar Adelaide)* | *Salmonella Agona (Salmonella enterica subsp. enterica serovar Agona)* | *Salmonella Derby (Salmonella enterica subsp. enterica serovar Derby)* | *Salmonella Salford (Salmonella enterica subsp. enterica serovar Salford)* |
| *Salmonella Senftenburg (Salmonella enterica subsp. enterica serovar Senftenberg)* | *Scutellospora dipurpurescens* | *Serratia spp.* | *Shewanella spp. (excluding Shewanella marisflavi)* |
| *Shigella spp.* | *Sindbis virus* | *Sinorhizobium adhaerens* | *Sinorhizobium meliloti* |
| *Sporosarcina pasteurii* | *Staphylococcus spp.* | *Stenotrophomonas spp.* | *Streptococcus spp.* |
| *Streptomyces rectiverticillatus* | *Streptoverticillium rectiverticillatum* | *Suillus granulatus* | *Sulfobacillus spp.* |
| *Sulfolobus spp.* | *Sulfurisphaera spp.* | *Tetrahymena spp.* | *Thermus spp.* |
| *Thiobacillus spp.* | *Toxoplasma spp.* | *Tritirachium shiotae* | *Tritirachium shiotae* |
| *Vaccinia virus (cow pox)* | *Vibrio alginolyticus* | *Vibrio cholerae (excluding serotype 01 and serotype 0139)* | *Vibrio parahaemolyticus (excluding VPAHPND strains with plasmid coding for Pir toxin homologues)* |
| *Vibrio vulnificus (excluding biovar II)* | *Wolinella succinogens* | *Xanthobacter spp.* | *Yersinia enterocolitica* |

**Appendix 2: List: Approved starter cultures**

**List of approved starter cultures**

|  |  |  |
| --- | --- | --- |
| *Acetobacter* spp. | *Aspergillus brasiliensis* | *Aspergillus oryzae*  |
| *Aspergillus niger* | *Bacillus acidopullulyticus* | *Bacillus amyloliquefaciens* |
| *Bacillus coagulans* | *Bacillus halodurans* | *Bacillus licheniformis* |
| *Bacillus subtilis* | Baker's yeast | *Bifidobacterium* spp. |
| *Brevibacterium linens* | Brewer's yeast | *Candida* spp. |
| *Chaetomium gracile* | *Citeromyces* spp. | *Clavispora* spp. |
| *Debaryomyces* spp*.* | *Dekkera* spp. | *Enterococcus durans* |
| *Enterococcus faecalis* | *Enterococcus faecium* | *Geotrichum candidum* |
| *Hansenula* spp*.* | *Hasegawaea* spp. | *Humicola insolens* |
| *Hyphopichia* spp. | *Issatchenkia* spp. | *Kluyveromyces* spp. |
| Lactic acid bacteria | *Lactobacillus* spp. | *Lactococcus* spp. |
| *Leuconostoc* spp. (*Oenococcus* spp.) | *Monascus* spp. | *Pediococcus pentosaceus* |
| *Penicillium camemberti* (also known as *Penicillium camembertii* and *Penicillium candidum*) | *Penicillium funiculosum* | *Penicillium roqueforti* (also known as *Penicillium roquefortii*) |
| *Phaffia* spp. | *Pichia* spp. | *Propionibacterium* spp. |
| *Rhizopus* spp. | *Saccharomyces* spp. | *Schizosaccharomyces* spp. |
| *Schwanniomyces* spp. | *Staphylococcus carnosus* | *Staphylococcus xylosus* |
| *Streptococcus cremoris* | *Streptococcus diacetilactis* | *Streptococcus durans* |
| *Streptococcus faecalis* | *Streptococcus lactis* | *Streptococcus salivarius* |
| *Streptococcus thermophilus* | *Streptomyces olivaceus* | *Streptomyces olivochromogenes* |
| *Streptomyces murinus* | *Streptomyces mobaraensis* (former name *Streptoverticillium mobaraensis*) | *Streptomyces rubiginosus* |
| *Streptomyces violaceoruber* | *Talaromyces emersonii (*former name *Penicillium emersonii*) | *Torulaspora* spp. |
| *Torulopsis* spp. | *Trichoderma harzianum* | *Trichoderma reesei* (former name *Trichoderma longibrachiatum*) |
| *Trichoderma viride* | Wine culture | Yoghurt/Kefir culture |
| *Zygoascus* spp. | *Zygosaccharomyces* spp. |  |