



Permit to import conditionally non-prohibited goods

This permit is issued under *Biosecurity Act 2015* Section 179 (1)

Permit: 0004425365

**Valid for: multiple consignments
 between 21 December 2020 and 21 December 2022**

This permit is issued to: The Walter and Eliza Hall Institute of Medical Research
 1G Royal Parade
 PARKVILLE VIC 3052
 Australia

Attention: Ms Wendy Carter

This permit is issued for the import of Biological products (Non-standard goods).

Exporter details:	Various exporters
Country of export:	Various countries

This permit includes the following good(s). Refer to the indicated page for details of the permit conditions:

1. Genetic material (including viable genetic expression systems) End use: In vitro use and/or in vivo use in laboratory organisms only Country of export: Various countries Country of origin: Various countries Permit Conditions: Replication incompetent viral vectors	Page 3
2. Genetic material (including viable genetic expression systems) End use: In vitro use and/or in vivo use in laboratory organisms only Country of export: Various countries Country of origin: Various countries Permit Conditions: Replication incompetent viral vectors	Page 7

NOTE: Where a good has more than one set of permit conditions please read each set to determine which set of permit conditions applies to a specific consignment.

----- **End of commodity list** -----

This permit is granted subject to the requirement that fees determined under section 592(1) are paid.

Lina Tze
 Delegate of the Director of Biosecurity

Date: 21 December 2020

Important information about this permit and the import of goods

Note: This permit covers Department of Agriculture, Water and the Environment biosecurity requirements. It is your responsibility to ensure all legal requirements relating to the goods described in this import permit are met. While you should rely on your own inquiries, the following information is provided to assist you in meeting your legal obligations in relation to the importation of the goods described in this import permit.

Authority to import

You are authorised to import the goods described in this import permit under the listed conditions.

Compliance with permit conditions and freedom from contamination

All imports may be subject to biosecurity inspection on arrival to determine compliance with the listed permit conditions and freedom from contamination. Imports not in compliance or not appropriately identified or packaged and labelled in accordance with the import conditions they represent may be subject to treatment, export or destruction at the importer's expense, or forfeited to the Commonwealth.

Compliance with other regulatory provisions

Additionally, all foods imported into Australia must comply with the provisions of the *Imported Food Control Act 1992*, and may be inspected and/or analysed against the requirements of the Australia New Zealand Food Standards Code.

All imports containing or derived from genetically modified material must comply with the *Gene Technology Act 2000*.

It is the importer's responsibility to identify and ensure they have complied with all requirements of any other regulatory organisations and advisory bodies prior to and after importation. Organisations include the Department of Home Affairs, the Department of Health, Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, Food Standards Australia New Zealand and any state agencies such as Departments of Agriculture and Health and Environmental Protection authorities. Importers should note that this list is not exhaustive.

Change of import conditions

Import conditions are subject to change at the discretion of the Director of Biosecurity. This permit may be suspended or revoked without notice.

Notification of import

Notification of the import must be provided to the Department of Agriculture, Water and the Environment for all imported goods other than goods imported as accompanied baggage or goods imported via the mail and not prescribed under *the Customs Act 1901*. Notification must be consistent with the Biosecurity Regulation 2016.

Valid import permit

The importer must hold a valid import permit at the time when the goods are brought or imported into Australian Territory.

The importer must verify that they hold a valid import permit in relation to the consignment by providing positive identification to the Department of Agriculture, Water and the Environment, by either:

- i. Submitting (or providing) the permit for biosecurity clearance.

OR

- ii. Providing any physical, digital or verbal information that allows the permit to be identified at the time of biosecurity clearance.

Provision of required documentation

All required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to the Department of Agriculture, Water and the Environment at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked "Attention Department of Agriculture, Water and the Environment". Documentation may include the import permit (or import permit number), government certification and invoice.

If the product description on the import permit varies from the identifying documentation provided for clearance, the importer is responsible for providing evidence to the biosecurity officer that the import permit covers the goods in the consignment.

Any documentation provided must comply with the Department of Agriculture, Water and the Environment's minimum documentation requirements policy.

Permit conditions

It is the importer's responsibility to ensure that the following permit conditions are met in relation to each consignment. Where more than one set of permit conditions is shown for a good please read each set of conditions to determine which applies to a specific consignment.

1. Replication incompetent viral vectors

This section contains permit conditions for the following commodity (or commodities):

- | |
|---|
| 1. Genetic material (including viable genetic expression systems) |
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1.1. Biosecurity Pathway

- a. These conditions allow for the import of the following products only:

Replication incompetent Retroviral, Lentiviral, and Adenoviral vectors only

- b. The goods must meet biosecurity requirements.

To demonstrate compliance with this requirement you must present the following on a Manufacturer's declaration:

- (1) A statement that the Retroviral vectors contain nucleic acid from the following:

- o Gag, pol, rev, and tat genes from HIV-1
- o Murine cationic amino acid transporter-1 (MCAT-1) gene
- o Long terminal repeat sequences from HIV-1
- o Murine leukaemia virus (MLV)
- o Long terminal repeats (LTRs) from Moloney murine leukaemia virus (MoMLV) or Murine stem cell virus (MSCV)
- o Vesicular stomatitis virus glycoprotein (VSV-G)

AND

- (2) A statement that the Lentiviral vectors contain nucleic acid from the following:

- o Gag, pol, rev, and tat genes from HIV-1
- o Long terminal repeat sequences from HIV-1
- o LTRs from Murine leukaemia virus (MLV)
- o Murine cationic amino acid transporter-1 (MCAT-1) genes
- o Vesicular stomatitis virus glycoprotein (VSV-G)

AND

- (3) A statement that the Adenoviral vectors contain nucleic acid from the following:

- o E2, E4, and L1-5 genes from human adenovirus type 5 (ad5)
- o Vesicular stomatitis virus glycoprotein (VSV-G)

AND

- (3) A statement that the viral vectors are replication incompetent.

AND

(4) A statement that the plasmids are cloning and expression vectors which have been deliberately constructed for that purpose, which are non-integrative and non-conjugative, and do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions, or which contain known autonomous genetic elements from any species, or “pathogenicity islands” or known bacterial virulence factors excluding antimicrobial resistance genes used to facilitate selection and plasmid replication factors.

AND

(5) A statement that the proteins, coding regions, and genetic information included in any vector are not derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species.

AND

(6) A statement that the non-coding regions, promoters, enhancers, tags, markers and other elements derived from microorganisms or infectious agents in the vectors do not encode a complete open-reading frame or gene and are not derived from or homologous to genes from microorganisms or infectious agents listed in Appendix 1.1. of this permit.

AND

(7) A statement that the vectors do not contain:

- 7.1. the whole genome of any organism or infectious agent
- 7.2. any known virulence factors*
- 7.3. any genetic material derived from or homologous to a gene from a microorganism or infectious agents listed in Appendix 1.1.

*Virulence factors are defined as any factor that contributes to a pathogen's ability to suppress or evade the hosts immune system, or expand host range.

The manufacturer's declaration must be from:

The Manufacturer

- c. All material for import must be grown using sterile media.
- d. Imported material and derivatives are not to be used with genes derived from and/or associated with, or homologous to those associated pathogens listed (Appendix [1 - 1](#)) without further assessment by the Department of Agriculture, Water and the Environment.
- e. Imported material and derivatives are not to be used in the synthesis of listed pathogens (Appendix [1 - 1](#)), or their homologues without further assessment by the Department of Agriculture, Water and the Environment.
- f. 1. Proteins, coding regions and genetic information included in any vector must not be derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from

any species.

2. Non-coding regions, promoters, enhancers, tags, markers and other elements derived from microorganisms or infectious agents which do not encode a complete open-reading frame or gene may be inserted into the viral vectors and plasmids. These elements must not be derived from or homologous to microorganisms or infectious agents listed in Appendix 1.1.

3. The goods must not be used for the synthesis of replication-competent microorganisms, infectious agents or homologues.

4. The vectors do not contain:

4.1. the whole genome of any organism or infectious agent

4.2. any known virulence factors*

4.3. any genetic material derived from or homologous to a gene from a microorganism or infectious agents listed in Appendix 1.1.

*Virulence factors are defined as any factor that contributes to a pathogen's ability to suppress or evade the hosts immune system, or expand host range.

g. **Post entry/end use conditions**

Approved end uses:

1. *in vitro* laboratory studies,
2. *in vivo* in laboratory organisms. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.

Additional written approvals* are required prior to direct or indirect use:

1. in plants,
2. in non-laboratory organisms e.g. chickens, sheep, cattle,
3. as veterinary vaccines and therapeutics.

* For information on how to obtain additional written approvals contact imports@agriculture.gov.au or call 1800 900 090.

It is the importers responsibility to ensure that the goods are labelled “*in-vitro or in-vivo use in laboratory organisms only*” on the smallest packaged unit, prior to distribution. The products may be labelled post entry.



Where applicable, the importer or end user must comply with:

1. International (e.g. [International Air Transport Association](#)) and domestic requirements concerning the safe handling, transport and labelling of biological material
2. AS/NZS 2243 Safety in Laboratories standards
3. [Office of the Gene Technology Regulator \(OGTR\)](#) requirements
4. The [Security Sensitive Biological Agents \(SSBA\) regulatory scheme](#).

h. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).
e.g. 1: Product XRab = Purified protein derived from rabbits
e.g. 2: Product AX = Synthetic antibiotic
e.g. 3: Comte = Cheese.

i. Under the [Biosecurity Charges Imposition \(General\) Regulation 2016](#) and Chapter 9, Part 2 of the [Biosecurity Regulation 2016](#), fees are payable to the Department of Agriculture, Water and the Environment for all services. Detail on how the department applies fees and levies may be found in the [Charging guidelines](#).

j. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

2. Replication incompetent viral vectors

This section contains permit conditions for the following commodity (or commodities):

2. Genetic material (including viable genetic expression systems)

2.1. Biosecurity Pathway

a. These conditions allow for the import of the following products only:
Adeno-associated virus vector constructs

b. The goods must meet biosecurity requirements.

To demonstrate compliance with this requirement you must present the following on a Manufacturer's declaration:

(1) A statement that the Adeno-associated virus vectors contain woodchuck hepatitis virus post-transcriptional regulatory element (WPRE) and are replication incompetent; and

(2) A statement that the plasmids are cloning and expression vectors which have been deliberately constructed for that purpose, which are non-integrative and non-conjugative, and do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions, or which contain known autonomous genetic elements from any species, or "pathogenicity islands" or known bacterial virulence factors excluding antimicrobial resistance genes used to facilitate selection and plasmid replication factors; and

(3) A statement that the proteins, coding regions, and genetic information included in any vector are not derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species; and

(4) A statement that the non-coding regions, promoters, enhancers, tags, markers and other elements derived from microorganisms or infectious agents in the vectors do not encode a complete open-reading frame or gene and are not derived from or homologous to microorganisms or infectious agents listed in Appendix 1.1. of this permit; and

(5) A statement that the vectors do not contain:

5.1. the whole genome of any organism or infectious agent

5.2. any known virulence factors*

5.3. any genetic material derived from or homologous to a gene from a microorganism or infectious agents listed in Appendix 1.1.

*Virulence factors are defined as any factor that contributes to a pathogen's ability to suppress or evade the hosts immune system, or expand host range.

The manufacturer's declaration must be from:

The Manufacturer.

c. All material for import must be grown using sterile media.

d. Imported material and derivatives are not to be used with genes derived from and/or associated with, or homologous to those associated pathogens listed ([Appendix 1 - 2](#))

without further assessment by the Department of Agriculture, Water and the Environment.

e. Imported material and derivatives are not to be used in the synthesis of listed pathogens (Appendix 1 - 2), or their homologues without further assessment by the Department of Agriculture, Water and the Environment.

f. 1. Proteins, coding regions and genetic information included in any vector must not be derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species.

2. The vectors may contain woodchuck hepatitis virus post-transcriptional regulatory element (WPRE) but do not contain:

2.1. the whole genome of any organism or infectious agent

2.2. any known virulence factors*

2.3. any genetic material derived from or homologous to a gene from a microorganism or infectious agents listed in Appendix 1.1.

*Virulence factors are defined as any factor that contributes to a pathogen's ability to suppress or evade the hosts immune system, or expand host range.

3. Non-coding regions, promoters, enhancers, tags, markers and other elements derived from microorganisms or infectious agents which do not encode a complete open-reading frame or gene may be inserted into the vectors. These elements must not be derived from or homologous to microorganisms or infectious agents listed in Appendix 1.1. of this permit.

4. The goods must not be used for the synthesis of replication-competent microorganisms, infectious agents or homologues.

g. **Post entry/end use conditions**

Approved end uses:

1. *in vitro* laboratory studies,

2. *in vivo* in laboratory organisms. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.

Additional written approvals* are required prior to direct or indirect use:

1. in plants,

2. in non-laboratory organisms e.g. chickens, sheep, cattle,

3. as veterinary vaccines and therapeutics.

* For information on how to obtain additional written approvals contact imports@agriculture.gov.au or call 1800 900 090.

It is the importers responsibility to ensure that the goods are labelled “*in-vitro or in-vivo use in laboratory organisms only*” on the smallest packaged unit, prior to distribution. The products may be labelled post entry.



Where applicable, the importer or end user must comply with:

1. International (e.g. [International Air Transport Association](#)) and domestic requirements concerning the safe handling, transport and labelling of biological material
2. AS/NZS 2243 Safety in Laboratories standards
3. [Office of the Gene Technology Regulator \(OGTR\)](#) requirements
4. The [Security Sensitive Biological Agents \(SSBA\) regulatory scheme](#).

h. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
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 3. describe the goods being imported (where not clear).
e.g. 1: Product XRab = Purified protein derived from rabbits
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e.g. 3: Comte = Cheese.
- i. Under the [Biosecurity Charges Imposition \(General\) Regulation 2016](#) and Chapter 9, Part 2 of the [Biosecurity Regulation 2016](#), fees are payable to the Department of Agriculture, Water and the Environment for all services. Detail on how the department applies fees and levies may be found in the [Charging guidelines](#).
- j. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

Appendix 1 - 1: List of infectious agents nucleic acid is not permitted to be derived from

Nucleic acid derived from the following microorganisms and viruses must NOT be imported using this import permit

Adenomatosis virus	African horse sickness virus	African swine fever virus
Avian influenza virus	Anatid herpesvirus 1 (duck enteritis virus, duck plague herpesvirus)	Aviadenoviruses (all viruses in the genus)
Bluetongue virus	<i>Babesia caballi</i>	Bovine herpesvirus 1
Bovine herpesvirus 4	Bovine respiratory syncytial virus	Bovine spongiform encephalopathy agent (prion)
Bovine viral diarrhoea virus 1 & 2 (bovine pestiviruses)	<i>Brucella abortus</i>	<i>Brucella canis</i>
<i>Brucella melitensis</i>	Caprine/ovine pox virus	Chronic wasting (prion)
Classical swine fever virus	Duck viral hepatitis virus	<i>Ehrlichia canis</i>
Epizootic hemorrhagic disease virus (EHDV)	Equine arteritis virus	Equine encephalitis viruses (eastern equine encephalitis virus, western equine encephalitis virus, Venezuelan equine encephalitis virus)
Equid herpesvirus 1, 2, 3 & 4	Equine influenza virus	<i>Francisella tularensis</i>
Foot-and-Mouth disease virus	Hantaan virus (Korean	<i>Histoplasma capsulatum</i> var.

	haemorrhagic fever virus)	<i>farciminosum</i>
Horse pox virus (vaccinia virus)	Human swine influenza with pandemic potential	Infectious bronchitis virus
Infectious bursal disease virus	Japanese encephalitis virus	<i>Leptospira interrogans</i> var. <i>canicola</i>
Louping ill virus	Lumpy skin disease virus	Lymphocytic choriomeningitis virus (Arenavirus)
Middle East respiratory syndrome (MERS) (Middle Eastern respiratory syndrome-related coronavirus)	Murine adenovirus	<i>Mycoplasma agalactiae</i>
<i>Mycoplasma capricolum</i> subsp. <i>capripneumoniae</i>	<i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> small colony (SC) type	Neorickettsia risticii
Newcastle disease virus	Ornithobacterium rhinotracheale	Peste-des-petits-ruminants virus
Plague (<i>Yersinia pestis</i>)	<i>Porcine circovirus 2</i>	Porcine epidemic diarrhoea virus
Porcine reproductive and respiratory syndrome virus	Porcine respiratory coronavirus	Porcine teschovirus 1 (polioencephalomyelitis virus, porcine enterovirus)
<i>Pseudorabies virus</i> (suid herpesvirus 1, Aujeszky's disease virus)	Rabbit haemorrhagic disease virus (rabbit calicivirus)	Rabbit fibroma virus (Shope fibroma virus)
Rabies virus	Rift Valley fever virus	Rinderpest virus

<i>Salmonella</i> Enteritidis	<i>Salmonella</i> Gallinarum	<i>Salmonella</i> Pullorum
Scrapie agent (prion)	Severe acute respiratory syndrome (SARS) (severe acute respiratory syndrome-related coronavirus)	Smallpox (Variola virus and Poxvirus variola)
Swine vesicular disease virus	<i>Taylorella equigenitalis</i>	<i>Theileria equi</i>
Transmissible gastroenteritis virus	Transmissible mink encephalopathy agent (prion)	<i>Treponema paraluis-cuniculi</i>
<i>Trypanosoma evansi</i>	Turkey rhinotracheitis virus (avian metapneumovirus, avian pneumovirus)	Viral haemorrhagic fevers of humans including Ebola haemorrhagic fever (Filoviridae), Marburg virus (Filoviridae), Lassa Fever (Arenaviridae) and Crimean-Congo hemorrhagic fever (Nairovirus)
Vesicular Stomatitis virus (VSV-G protein is permitted)	Visna/maedi (Maedi-visna) virus	West Nile virus
Other agents of transmissible spongiform encephalopathies	All plant pathogens (viruses, bacteria, fungi and stramenopiles)	

Appendix 1 - 2: List of infectious agents nucleic acid is not permitted to be derived from

Nucleic acid derived from the following microorganisms and viruses must NOT be imported using this import permit

Adenomatosis virus	African horse sickness virus	African swine fever virus
Avian influenza virus	Anatid herpesvirus 1 (duck enteritis virus, duck plague herpesvirus)	Aviadenoviruses (all viruses in the genus)
Bluetongue virus	<i>Babesia caballi</i>	Bovine herpesvirus 1
Bovine herpesvirus 4	Bovine respiratory syncytial virus	Bovine spongiform encephalopathy agent (prion)
Bovine viral diarrhoea virus 1 & 2 (bovine pestiviruses)	<i>Brucella abortus</i>	<i>Brucella canis</i>
<i>Brucella melitensis</i>	Caprine/ovine pox virus	Chronic wasting (prion)
Classical swine fever virus	Duck viral hepatitis virus	<i>Ehrlichia canis</i>
Epizootic hemorrhagic disease virus (EHDV)	Equine arteritis virus	Equine encephalitis viruses (eastern equine encephalitis virus, western equine encephalitis virus, Venezuelan equine encephalitis virus)
Equid herpesvirus 1, 2, 3 & 4	Equine influenza virus	<i>Francisella tularensis</i>
Foot-and-Mouth disease virus	Hantaan virus (Korean	<i>Histoplasma capsulatum</i> var.

	haemorrhagic fever virus)	<i>farciminosum</i>
Horse pox virus (vaccinia virus)	Human swine influenza with pandemic potential	Infectious bronchitis virus
Infectious bursal disease virus	Japanese encephalitis virus	<i>Leptospira interrogans</i> var. <i>canicola</i>
Louping ill virus	Lumpy skin disease virus	Lymphocytic choriomeningitis virus (Arenavirus)
Middle East respiratory syndrome (MERS) (Middle Eastern respiratory syndrome-related coronavirus)	Murine adenovirus	<i>Mycoplasma agalactiae</i>
<i>Mycoplasma capricolum</i> subsp. <i>capripneumoniae</i>	<i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> small colony (SC) type	Neorickettsia risticii
Newcastle disease virus	Ornithobacterium rhinotracheale	Peste-des-petits-ruminants virus
Plague (<i>Yersinia pestis</i>)	<i>Porcine circovirus 2</i>	Porcine epidemic diarrhoea virus
Porcine reproductive and respiratory syndrome virus	Porcine respiratory coronavirus	Porcine teschovirus 1 (polioencephalomyelitis virus, porcine enterovirus)
<i>Pseudorabies virus</i> (suid herpesvirus 1, Aujeszky's disease virus)	Rabbit haemorrhagic disease virus (rabbit calicivirus)	Rabbit fibroma virus (Shope fibroma virus)
Rabies virus	Rift Valley fever virus	Rinderpest virus

<i>Salmonella</i> Enteritidis	<i>Salmonella</i> Gallinarum	<i>Salmonella</i> Pullorum
Scrapie agent (prion)	Severe acute respiratory syndrome (SARS) (severe acute respiratory syndrome-related coronavirus)	Smallpox (Variola virus and Poxvirus variola)
Swine vesicular disease virus	<i>Taylorella equigenitalis</i>	<i>Theileria equi</i>
Transmissible gastroenteritis virus	Transmissible mink encephalopathy agent (prion)	<i>Treponema paraluis-cuniculi</i>
<i>Trypanosoma evansi</i>	Turkey rhinotracheitis virus (avian metapneumovirus, avian pneumovirus)	Viral haemorrhagic fevers of humans including Ebola haemorrhagic fever (Filoviridae), Marburg virus (Filoviridae), Lassa Fever (Arenaviridae) and Crimean-Congo hemorrhagic fever (Nairovirus)
Vesicular Stomatitis virus (VSV-G protein is permitted)	Visna/maedi (Maedi-visna) virus	West Nile virus
Other agents of transmissible spongiform encephalopathies	All plant pathogens (viruses, bacteria, fungi and stramenopiles)	

----- **End of permit conditions** -----