Australian Government
Department of Agriculture and Water Resources

Permit to import conditionally non-prohibited goods

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

Permit: 0001693366

Valid for: multiple consignments between 24 October 2017 and 24 October 2019

This permit is issued to: Garvan Institute of Medical Research
384 Victoria Street
Darlinghurst NSW 2010
Australia

Attention: Dr Kharen Doyle

This permit is issued for the import of Biological products (Standard goods).

Exporter details:	Various exporters

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

1. Genetic material		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Genetic material purified and derived from standard laboratory microorganisms including viruses	Page 5
2. Genetic material		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Low risk genetic material and vectors	Page 7
3. Cell lines and/or supernatant fluid		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Cell lines of laboratory animal and human origin	Page 9
4. Purified or refined laboratory reagents		

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

Jaime Crowe
Delegate of the Director of Biosecurity Date: 24 October 2017

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End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Purified/refined laboratory reagents	Page 11
5. Animal fluids and tissues (ex reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Low risk animal fluids and tissues excluding reproductive material	Page 13
6. Animal fluids and tissues (ex reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues from ovines, caprines, bovines, cervines, camelids and giraffids only	Page 15
7. Animal fluids and tissues (ex reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues excluding reproductive material sourced from equines only	Page 17
8. Animal fluids and tissues (ex reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues excluding reproductive material sourced from porcines only	Page 19
9. Cell lines and/or supernatant fluid		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Cell lines from non-laboratory animals	Page 21
10. Antibodies		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Antibodies purified and raised against synthetic material or antigens from multicellular organisms	Page 24
11. Antisera		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	

Permit Conditions:	Antisera sourced from low risk species raised against microorganisms including viruses	Page 26
12. Human fluids and tissues		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Human fluids and tissues that are not known to be infected	Page 28
13. Microorganisms (including viruses)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Standard laboratory microorganisms and infectious agents	Page 30
14. Diagnostic and research only kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Diagnostic kit description:	Not for testing microorganisms, viruses or prions inside a laboratory	
Permit Conditions:	Diagnostic kits not testing for microorganisms, viruses and prions for use in a laboratory	Page 32

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 ----------

Important information about this permit and the import of goods

Note: This permit covers Department of Agriculture and Water Resources 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 Immigration and Border Protection, the Department of Health, Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, the Department of the Environment, 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 and Water Resources 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 when the goods are presented for clearance.

The importer must verify that an import permit has been issued in relation to the consignment by one of the following means:

i. The positive identification of the import permit to the Department of Agriculture and Water Resources at the time that the goods are being processed for biosecurity clearance, such as by presenting the import permit.

OR

ii. Any form of physical, digital or verbal correspondence presented with information that allows an import permit to be identified.

Provision of required documentation

All required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to the Department of Agriculture and Water Resources 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 and Water Resources". 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 and Water Resource'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. Genetic material purified and derived from standard laboratory microorganisms including viruses

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

1.	Genetic material

1.1. Biosecurity Pathway

a. **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.

b. These conditions apply to genetic material derived from microorganisms and viruses in the low risk microorganisms (including viruses) (Appendix 1) list including:

1. Transgenes (the specific gene of interest) from microorganisms and viruses, listed above, in purified cloning vectors and expression vectors i.e. bacterial plasmids, cosmid vectors, yeast artificial chromosomes, bacterial artificial chromosomes, human immunodeficiency virus (HIV) Lentivirus vectors and bacteriophages.
2. The cloning vectors may include the whole genome from any of the microorganisms and viruses listed above.
3. The cloning vectors may include genetic material derived from multicellular organisms.
4. These conditions do not permit the import of cultures of the above listed microorganisms and viruses.

c. The goods must be clearly labelled with the name of the source microorganism or virus.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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

4. in culturing or isolating microorganisms and infectious agents.

*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.

e. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

f. 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 BICON Non-Commodity Cargo Clearance case for further information.

2. Low risk genetic material and vectors

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

2. Genetic material

2.1. Biosecurity Pathway

a. **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.

b. These conditions allow for the importation of:

1. Purified genetic material from multicellular organisms (excluding plants and fungi); and/or
2. Purified cloning vectors and expression systems i.e. bacterial plasmids, cosmid vectors, yeast artificial chromosomes, bacterial artificial chromosomes and bacteriophages may be imported "empty" or may contain transgenes (the specific gene of interest) from multicellular organisms (excluding plants or fungi) only.

These conditions do NOT allow the importation of:

1. Cloning vectors or expression systems that contain transgenes (the specific gene of interest) derived from microorganisms (including viruses).
2. Genetic material derived from plants
3. Genetic material derived from fungi

c. **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.

d. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

e. 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 BICON Non-Commodity Cargo Clearance case for further information.

3. Cell lines of laboratory animal and human origin

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

3. Cell lines and/or supernatant fluid

3.1. Biosecurity Pathway

a. **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.

b. The following conditions apply to cell lines and/or supernatant fluid from humans, guinea pigs, rats, mice, hamsters, rabbits, insects, arachnids, amphibians, reptiles, non-salmonid finfish and hybridomas (combinations) of these species.

1. Either

   1.1 the cell line must be derived from animals with no history of clinical signs of infectious diseases, or

   1.2 The cell line must show no signs of contamination, including cytopathic effects, with adventitious infectious agent or microorganism.
2. The cell line must not have been inoculated with any live, or whole inactivated, microorganisms, viruses or prions (other than viral DNA which has been used to immortalise the cell line).
3. The cell line must not have been inoculated with any derivatives of microorganisms, viruses or prions (other than viral DNA which has been used to immortalise the cell line).

c. **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.

d. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

e. 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 BICON Non-Commodity Cargo Clearance case for further information.

4. Purified/refined laboratory reagents

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

4.	Purified or refined laboratory reagents

4.1. Biosecurity Pathway

a. **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.

b. These conditions allow for the import of:

1. **Purified and animal derived:**
   1.1 albumins, including bovine serum albumin
   1.2 carboxylic acids
   1.3 co-factors
   1.4 enzymes
   1.5 enzyme inhibitors
   1.6 growth factors
   1.7 hormones
   1.8 lipids (this includes fats, waxes, sterols, fat-soluble vitamins (e.g. A, D, E, and K), glycerides, phospholipids and their derivatives.)
   1.9 molecules (excluding genetic material)
   1.10 proteins (this includes derivatives e.g. peptides, amino acids). This case does not allow the import of prions.
   1.11 vitamins.
2. **Fermented and then purified:**
   2.1 laboratory material derived from a fermentation process e.g. antibiotics and enzymes (it is the importers responsibility to provide documentation to support this claim).
3. **Purified and bacterial (including recombinant bacterial) and/or fungi derived:**
   3.1 antibiotics (e.g. antibiotic sensitivity discs)
   3.2 enzymes (e.g. polymerases, modifying enzymes and restriction enzymes)
   3.3 growth factors
   3.4 hormones
   3.5 lipids (this includes fats, waxes, sterols, fat-soluble vitamins (e.g. A, D, E, and K), glycerides, phospholipids and their derivatives.)
   3.6 molecules (excluding genetic material)
   3.7 proteins (this includes derivatives e.g. peptides, amino acids). This case does not allow the import of prions.

c. The products must be imported in quantities of no greater than 20 ml or 20 g for each individually packaged unit.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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
4. in culturing or isolating microorganisms and infectious agents.

*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.

e. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

f. 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 BICON Non-Commodity Cargo Clearance case for further information.

5. Low risk animal fluids and tissues excluding reproductive material

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

5. Animal fluids and tissues (ex reproductive material)

5.1. Biosecurity Pathway

a. The following conditions apply to:

1. animal fluids and tissues sourced from all species (excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 20 mL or 20 g per individually packaged unit.
2. antisera sourced from all species (excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 20 mL or 20 g per individually packaged unit. The antisera must only be raised against synthetic material or against antigens derived from multicellular organisms.
3. sera, plasma and blood proteins sourced from all species (excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 20 mL or 20 g per individually packaged unit.
4. urine sourced from all species (excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 500 mL or 500 g per individually packaged unit.
5. animal fluids (excluding reproductive material) sourced from all species and dried onto filter paper.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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
4. in culturing or isolating microorganisms and infectious agents.

*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.

c. **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.

d. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

e. 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 BICON Non-Commodity Cargo Clearance case for further information.

6. Animal fluids and tissues from ovines, caprines, bovines, cervines, camelids and giraffids only

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

6. Animal fluids and tissues (ex reproductive material)

6.1. Biosecurity Pathway

a. The following conditions apply to:
   1. fluids and tissues (excluding reproductive material) sourced from ovines, caprines, bovines, cervines, camelids and giraffids.
   2. antisera derived from these species. The antisera must only be raised against synthetic material or against antigens derived from multicellular organisms. Antisera raised against microorganisms (including viruses and prions) are not permitted under these conditions.
   3. sera, plasma and blood proteins from these species.
   4. urine sourced from these species if imported in quantities of no greater than 500 mL or 500 g per individually packaged unit.

b. The product must be sourced from animals not knowingly infected.

c. The product must be sourced from animals born, raised and residing in one of the following countries:
Australia, Austria, Belgium, Bosnia and Herzegovina, Canada, Chile, Croatia, Cyprus, Czechia (Czech Republic), Denmark, Estonia, Former Yugoslav Republic of Macedonia, France, Finland, Germany, Hungary, Iceland, Indonesia, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Iceland, Malta, Mexico, Montenegro, Netherlands, New Caledonia, New Zealand, Norway, Poland, Portugal, Romania, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States of America, Vanuatu.

d. If the product cannot meet the above conditions it must be subjected to gamma irradiation at 50 kGy (5 Mrad) before it is released to the importer. Irradiation at 50 kGy at a Department of Agriculture and Water Resources approved facility is mandatory even if the product has been irradiated prior to import into Australia.

e. The products (other than urine) must be imported in quantities of no greater than 20 mL or 20 g for each individually packaged unit.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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
4. in culturing or isolating microorganisms and infectious agents.

*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.

g. **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.

h. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

i. 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 BICON Non-Commodity Cargo Clearance case for further information.

7. Animal fluids and tissues excluding reproductive material sourced from equines only

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

7. Animal fluids and tissues (ex reproductive material)

7.1. Biosecurity Pathway

a. The following conditions apply to:
   1. fluids and tissues (excluding reproductive material) sourced from equines.
   2. antisera derived from these species. The antisera must only be raised against synthetic material or against antigens derived from multicellular organisms. Antisera raised against microorganisms (including viruses and prions) are not permitted under these conditions.
   3. sera, plasma and blood proteins from these species.
   4. urine sourced from these species if imported in quantities of no greater than 500 mL or 500 g per smallest packaged unit.

b. The products (other than urine) must be imported in quantities of no greater than 20 mL or 20 g for each individually packaged unit.

c. The product must be sourced from animals not knowingly infected.

d. The product must be sourced from animals born, raised and residing in one of the following countries:
Argentina, Australia, Austria, Belgium, British Honduras, British Virgin Islands, Canada, Chile, Cook Islands, Cyprus, Denmark, Fiji, Finland, France, French Polynesia, Germany, Greece, Greenland, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Netherlands, New Caledonia, New Zealand, Norway, Papua New Guinea, Portugal, Singapore, Spain, Sweden, Switzerland, United Kingdom, United States of America, Vanuatu, Falkland Islands.

e. If the product is not sourced from one of the countries listed above it must be subjected to gamma irradiation at 50 kGy (5 Mrad) before it is released to the importer. Irradiation at 50 kGy at a Department of Agriculture and Water Resources approved facility is mandatory even if the product has been irradiated prior to import into Australian territory.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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
4. in culturing or isolating microorganisms and infectious agents.

*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.

g. **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.

h. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

i. 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 BICON Non-Commodity Cargo Clearance case for further information.

8. Animal fluids and tissues excluding reproductive material sourced from porcines only

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

8.	Animal fluids and tissues (ex reproductive material)

8.1. Biosecurity Pathway

a. **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.

b. The following conditions apply to:

1. fluids and tissues (excluding reproductive material) sourced from porcines.
2. antisera derived from these species. The antisera must only be raised against synthetic material or against antigens derived from multicellular organisms. Antisera raised against microorganisms (including viruses and prions) are not permitted under these conditions.
3. sera, plasma and blood proteins from these species.
4. urine sourced from these species if imported in quantities of no greater than 500 mL or 500 g per individually packaged unit.

c. **Sourcing conditions**

1. The product must be sourced from animals not knowingly infected.
2. The product must be sourced from animals born, raised and residing in one of the following countries:

   Australia, Austria, Belgium, Canada, Chile, Cyprus, Denmark, France, Finland, Netherlands, Iceland, Ireland, Japan, Malta, New Caledonia, New Zealand, Norway, Singapore, Spain, Sweden, United Kingdom, United States of America, Vanuatu.

   OR
3. If the product cannot meet both points 1 and 2 above it must be subjected to gamma irradiation at 50 kGy (5 Mrad) before it is released to the importer. Irradiation at 50 kGy at a Department of Agriculture and Water Resources approved facility is mandatory even if the product has been irradiated prior to import into Australian territory.

d. The products (other than urine) must be imported in quantities of no greater than 20 mL or 20 g for each individually packaged unit.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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
4. in culturing or isolating microorganisms and infectious agents.

*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.

f. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

g. 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 BICON Non-Commodity Cargo Clearance case for further information.

9. Cell lines from non-laboratory animals

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

9.	Cell lines and/or supernatant fluid

9.1. Biosecurity Pathway

a. The following conditions apply to cell lines and/or supernatant fluid derived from all animal species, excluding humans, guinea pigs, rats, mice, hamsters, rabbits, insects, arachnids, amphibians, reptiles, non-salmonid finfish and hybridomas of these species. The import permit does not allow for the importation of primary cells.

b. The cell line must be free of contamination and infectious disease, and must not be inoculated with live or whole inactivated microorganisms, viruses or prions, or any of their derivatives.

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

1. A statement that the cell line has shown no signs of contamination including cytopathic effects, or adventitious microbial contamination (including viral contamination).
2. A statement that the cell line has not been inoculated with any live, or whole inactivated, microorganisms, viruses or prions (other than viral DNA which has been used to immortalise the cell line).
3. A statement that the cell line has not been inoculated with any derivatives of microorganisms, viruses or prions (other than viral DNA which has been used to immortalise the cell line).
4. Either

   4.1 A statement that the cell line is less than 2 years old and was derived from animals with no history or clinical signs of infectious disease, or

   4.2 A statement that the cell line is greater than 2 years old.

c. For cell lines and media derived from bovine, porcine, ovine, caprine, equine, avian or cervine animals, additional evidence must be presented to demonstrate freedom from disease.

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

For bovine: A statement that the cell line and/or bovine derived media used to support the cell line has been sourced from animals free of foot and mouth disease and rinderpest, or the cell line/media has been tested and found free of these pathogens.

For porcine: A statement that the cell line and/or porcine derived media used to support the cell line has been sourced from animals free of foot and mouth disease, African swine fever, classical swine fever and swine vesicular disease, or the cell line/media has been tested and found free of these pathogens.

For ovine or caprine: A statement that the cell line and/or ovine/caprine derived media used to support the cell line has been sourced from animals free of foot and mouth disease, rinderpest, peste des petis ruminants and ovine/caprine pox, or the cell line/media has been tested and found free of these pathogens.

For equine: A statement that the cell line and/or equine derived media used to support the cell line have been sourced from animals free from African horse sickness, or the cell line/media has been tested and found free of these pathogens.

For avian: A statement that the cell line and/or avian derived media used to support the cell

line has been sourced from animals free from avian influenza, Newcastle disease and virulent infectious bursal disease, or the cell line/media has been tested and found free of these pathogens.

For cervine: A statement that the cell line and/or cervine derived media used to support the cell line has been sourced from animals free of foot and mouth disease and rinderpest virus.

d. **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.

e. **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.

f. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

g. 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 BICON Non-Commodity Cargo Clearance case for further information.

10. Antibodies purified and raised against synthetic material or antigens from multicellular organisms

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

10. Antibodies

10.1. Biosecurity Pathway

a. This import permit covers the requirements for the importation of antibodies purified and raised against multicellular organisms (plants and animals) or synthetic (non-biological) material only.

This import permit does not cover the requirements for the importation of antibodies which are suspended in animal blood products (sera).

b. The products must be imported in quantities of no greater than 20 ml or 20 g for each individually packaged unit.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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
4. in culturing or isolating microorganisms and infectious agents.

*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.

d. **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.

e. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

f. 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 BICON Non-Commodity Cargo Clearance case for further information.

11. Antisera sourced from low risk species raised against microorganisms including viruses

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

11. Antisera

11.1. Biosecurity Pathway

a. Products imported under this permit must be sourced from low risk species raised against the standard laboratory microorganisms (including viruses) list (Appendix 1).

Low risk species are defined as all species excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids.

b. The products must be imported in quantities of no greater than 20 ml or 20 g for each individually packaged unit.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
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
4. in culturing or isolating microorganisms and infectious agents.

*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.

d. **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.

e. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

f. 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 BICON Non-Commodity Cargo Clearance case for further information.

12. Human fluids and tissues that are not known to be infected

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

12. Human fluids and tissues

12.1. Biosecurity Pathway

a. **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.

b. Human fluids and tissues may not be imported for the purpose of screening for the following infectious diseases:

1. Cholera
2. Highly pathogenic avian influenza (human)
3. Human swine influenza with pandemic potential
4. Middle East respiratory syndrome
5. Plague
6. Rabies
7. Severe acute respiratory syndrome (SARS)
8. Smallpox
9. Viral haemorrhagic fevers of humans
10. Yellow fever (in Northern Australia)
11. Any disease that is exotic to Australia

c. There is no requirement for a manufacturer or importer declaration to accompany samples imported into Australian territory.

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

1. These conditions allow for the importation of human fluids and tissues, not known to be infected, for *in vitro* laboratory studies (or *in vivo* use in laboratory organisms) only.
2. Laboratory organisms are those defined in the following list and must be contained under laboratory or animal house conditions: guinea pigs, hamsters, mice, rats, rabbits, or micro-organisms. Work in all other animals and plants is not permitted.
3. These conditions do not permit the direct or indirect exposure of the imported materials or derivatives to non-laboratory organisms or plants.
4. It is the end user's responsibility to ensure that the goods adhere to any Therapeutic Goods Association (TGA) regulatory requirements.
5. It is the importer's responsibility to ensure that the goods are labelled '*in vitro* use or *in vivo* use in laboratory organisms only' or equivalent on the smallest packaged unit prior to distribution.

6. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243.3:2010 Safety in Laboratory Standards.
7. The importer must undertake a risk assessment to ensure any specific hazards associated with *in vitro* use or *in vivo* use in laboratory animals are managed using appropriate work practices including use of any standard precautions as outlined in the Australian Guidelines for the prevention and Control of Infection in Healthcare.
8. It is the end user's responsibility to ensure that all products are used in accordance with the Office of the Gene Technology Regulator (OGTR) and Therapeutic Goods Administration (TGA) requirements.
9. It is the importer's responsibility to ensure compliance with all international (e.g. International Air Transport Association (IATA)) and domestic requirements concerning the safe handling, transport and labelling of biological material.

e. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

f. 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 BICON Non-Commodity Cargo Clearance case for further information.

13. Standard laboratory microorganisms and infectious agents

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

13.	Microorganisms (including viruses)

Some products may require specialised storage and/or handling.

13.1. Biosecurity Pathway

a. The product must be a standard laboratory microorganism.

Please refer to the standard laboratory microorganisms (including viruses) list (Appendix 1) table to determine if the product is considered a standard laboratory microorganism.

This permit also allows the importation of the following:

1. Transgenes (the specific gene of interest) from the microorganisms and viruses listed in the standard laboratory microorganisms list may also be imported in purified cloning vectors and expression vectors as listed in note below.

2. The microorganisms and viruses listed may also contain cloning vectors and expression vectors as listed in note below, and DNA inserts from species listed in standard laboratory microorganisms list. The cloning vectors and expression vectors may be imported "empty" or may contain genetic material from either:

   2.1. multicellular organisms (excluding plants or fungi), or
   2.2. any microorganism/s and viruses listed in the standard laboratory microorganisms list.

   Note: Permitted purified cloning vectors and expression vectors include bacterial plasmids, cosmid vectors, yeast artificial chromosomes, bacterial artificial chromosomes, human immunodeficiency virus (HIV) vectors and bacteriophages. Viral vectors, other than human immunodeficiency virus (HIV) vectors, are not permitted.

   The microorganisms listed may also be imported on a non-biological matrix (e.g. biological indicators, spore strips).

b. Each culture must be clearly identified.

To demonstrate compliance with this requirement you must present the following on a Product label, Invoice, Manufacturer's declaration, Exporter's declaration or Supplier's declaration:

The scientific name of the microorganism.

Cultures must be pure cultures (unless otherwise specified by the import permit) and labelled with the scientific name of the organism as it appears on the import permit including genus, species and any other criteria e.g. subspecies, strain, biotype, serotype, pathovar, variety etc.

c. **Post Entry Requirements**

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 of the imported goods (including their derivatives):

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

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.

d. **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.

e. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

f. 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 BICON Non-Commodity Cargo Clearance case for further information.

14. Diagnostic kits not testing for microorganisms, viruses and prions for use in a laboratory

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

14. Diagnostic and research only kits

14.1. Biosecurity Pathway

a. The diagnostic kits must only contain approved materials in volumes no greater than 20 g or 20 ml and must not contain any viruses, bacteria or any other microorganisms.

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

1. A statement that the diagnostic kit/s and/or research kit/s do not contain any viruses, bacteria or any other microorganisms.
2. A statement that the diagnostic kit/s and/or research kit/s do not contain any antigens derived from viruses, bacteria or any other microorganisms.
3. A statement that the diagnostic kit/s do not test for antibodies raised against viruses, bacteria or any other microorganisms.
4. A statement that the only animal (including human) derived materials which may be contained in the kits are:
   4.1 antibodies purified and raised against synthetic material or against antigens derived from multicellular organisms, and/or
   4.2 antigens derived from synthetic material or multicellular organisms, and/or
   4.3 laboratory reagents including animal sera, purified animal proteins, hormones, albumins (including bovine serum albumin), enzymes and lipids, and
   4.4 in volumes of no greater than 20 g or 20 ml per individually packaged unit.
5. For reagents in individual quantities greater than 20 g or 20 ml, the animal (including human) derived material is no greater than 20 g or 20 ml per individually packaged unit.

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

Approved end uses:

1. *in vitro* laboratory studies.

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

1. *in vivo* in laboratory organisms. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions
2. in plants
3. in non-laboratory organisms e.g. chickens, sheep, cattle
4. as veterinary vaccines and therapeutics
5. in culturing or isolating microorganisms and infectious agents.

It is the importers responsibility to ensure that the goods are labelled "*in-vitro 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.

c. **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.

d. 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 and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

e. 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 BICON Non-Commodity Cargo Clearance case for further information.

Appendix 1: Standard laboratory microorganisms (including viruses)

The following list contains low risk microorganisms, including viruses. These microorganisms are endemic (occur in Australia) and are commonly imported by laboratories in Australia.

Achromobacter spp.	*Acidianus spp.*	*Acidiphilium* spp.
Acidithiobacillus spp.	Adeno-associated virus	*Aeromonas hydrophila*
Alicyclobacillus spp.	*Aneurinibacillus migulanus (*formerly *Bacillus migulanus)*	*Aspergillus* spp.
Aquifex spp.	*Azotobacter* spp.	*Bacillus atrophaeus (formerly Bacillus subtilis var. niger)*
Bacillus brevis (now known as *Brevibacillus brevis*)	*Bacillus cereus excluding Biovar anthracis*	*Bacillus licheniformis*
Bacillus megaterium (excluding pv. cerealis)	*Bacillus pumilus (also known as Bacillus mesentericus and Bacillus aminoglucosidicus)*	*Bacillus sphaericus*
Bacillus stearothermophilus	*Bacillus subtilis*	*Bacteroides spp.*
Bartonella spp.	*Bordetella* spp.	*Botryococcus* spp.
Brachyspira spp.	*Brevibacillus* spp. (excluding *B. laterosporus*)	*Burkholderia pseudomallei*
Campylobacter spp.	*Caulobacter spp.*	*Chlamydia trachomatis*
Chlamydophila pneumonia	*Chryseobacterium* spp. (excluding *C. scophthalmum*)	*Citrobacter spp.*
Clostridium spp.	*Corynebacterium* spp. (excluding *C. pseudotuberculosis*)	*Cronobacter* spp.
Cryptococcus spp.	*Cryptomonas* spp.	*Cryptosporidium* spp.
Desulfobacter spp.	*Desulfovibrio* spp.	*Entamoeba* spp.
Enterobacter spp.	*Enterococcus* spp.	Enterovirus (human origin only, and excluding swine vesicular disease virus and human enterovirus C)
Escherichia spp.	*Ferroplasma* spp.	*Geobacillus* spp.
Geobacter spp.	*Giardia* spp.	*Haemophilus* spp.
Helicobacter 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*	*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 anisopilae*	*Methanococcus* spp.
Morganella spp.	*Moraxella spp. (includes subgen. Branhamella and subgen. Moraxella) (excluding M. anatipestifer)*	Murine cytomegalovirus (MCMV)
Murine leukaemia virus	*Mycobacterium* spp. (excluding *M. bovis* and *M. caprae*)	*Mycoplasma pneumoniae*
Neisseria spp.	*Nippostrongylus brasiliensis*	Parainfluenza virus (human)
Pediococcus spp.	*Penicillium chrysogenum*	*Porphyromonas* spp.
Proteus spp.	*Providencia* spp.	*Pseudomonas fluorescens (excluding biovar II)*
Pseudomonas aeruginosa	*Pseudomonas putida*	*Rhodobacter* spp.
Rhodococcus spp.	*Roseomonas* spp.	*Rubella virus*
Rubrivivax spp.	*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)	*Serratia* spp.	*Shewanella spp.* (excluding *Shewanella marisflavi)*
Shigella spp.	*Sindbis virus*	*Staphylococcus* spp.
Stenotrophomonas spp.	*Streptococcus* spp.	*Sulfobacillus* spp.
Sulfolobus spp.	*Sulfurisphaera* spp.	*Tetrahymena* spp.
Thermus spp.	*Thiobacillus* spp.	*Toxoplasma* spp.
Vaccinia virus (cow pox)	*Vibrio alginolyticus*	*Vibrio cholerae* (excluding serotype 01 and serotype 0139)
Vibrio parahaemolyticus (excluding VP_{AHPND} strains with plasmid coding for Pir toxin homologues)	*Vibrio vulnificus* (excluding biovar II)	*Yersinia enterocolitica*

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