Australian Government
Department of Agriculture, Fisheries and Forestry

Permit to import conditionally non-prohibited goods

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

Permit: [redacted]

Valid for: multiple consignments between 4 November 2022 and 23 November 2024

This permit is issued to: [redacted]

AUSTRALIA

Attention: Dr [redacted]

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. 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 free from listed diseases	Page 6
2. Animal fluids and tissues (excl. viable 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 avians only	Page 9
3. 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 12
4. Antibodies		

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

[redacted]

Delegate of the Director of Biosecurity

Date: 04 November 2022

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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:	Antibodies produced in recombinant systems or raised against recombinant antigens (Standard Permit)	Page 14
5. 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, insect and human origin	Page 17
6. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Nucleic acid amplification (e.g. PCR) test kits (Standard)	
Permit Conditions:	Nucleic Acid Amplification (NAA) test kits	Page 19
7. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Test kits testing for human conditions, excl. Listed Human Diseases and zoonotic diseases (Standard)	
Permit Conditions:	Diagnostic test kits excluding those testing for Listed Human Diseases and zoonotic diseases	Page 21
8. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Test kits not testing for disease agents (Standard)	
Permit Conditions:	Test kits not testing for disease agents	Page 24
9. 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 from multicellular organisms (Including listed vectors) and vectors	Page 26
10. 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 microorganisms and viruses (excluding listed species)	Page 28
11. 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 (and derivatives)	Page 30

12. Purified laboratory reagents, toxins and venoms		
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 laboratory material, laboratory reagents, toxins and venoms	Page 33
13. Animal fluids and tissues (excl. viable 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 (excl. viable reproductive material) sourced from captive primates only	Page 36
14. Animal fluids and tissues (excl. viable 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 ovines and caprines only	Page 39
15. Animal fluids and tissues (excl. viable 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 bovines only	Page 42
16. Animal fluids and tissues (excl. viable 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 cervines (deer) only	Page 45
17. Animal fluids and tissues (excl. viable 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 camelids only	Page 48
18. Animal fluids and tissues (excl. viable 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 suids (porcines) only	Page 51
19. 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 54

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, Fisheries and Forestry import conditions. It is the permit holder's responsibility to ensure all legal requirements relating to the goods described in this permit are met. While the permit holder should rely on their own inquiries, the following information is provided to assist the permit holder in meeting legal obligations in relation to the importation of the goods described in this permit.

Information about this permit

Authority to import

The permit holder is authorised to import the goods described in this permit subject to the listed conditions specified in this permit.

Compliance with permit conditions and assessment and management of biosecurity risk

All imports are subject to biosecurity control and may be subject to biosecurity inspection on arrival to determine compliance with the listed permit conditions and to assess the level of biosecurity risk associated with the goods. Imports that do not comply with the import conditions specified in the permit may present an unacceptable level of biosecurity risk and may be subject to biosecurity measures that may include treatment, export or destruction at the permit holder's expense or forfeited to the Commonwealth.

Additionally, non-compliance with import permit conditions may constitute an offence or contravention of a civil penalty provision under section 187 of the *Biosecurity Act 2015*.

Change of import conditions

The Director of Biosecurity may, in accordance with section 180 of the *Biosecurity Act 2015* vary or revoke the conditions on a permit or impose further conditions.

General information about importing goods

Notification of import

Notification of the import must be provided to the Department of Agriculture, Fisheries and Forestry 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,* or where other exceptions specified in the *Biosecurity Regulation 2016* apply. Notification must be provided in accordance with section 120 of the *Biosecurity Act 2015* and Part 1 of Chapter 2 of the *Biosecurity Regulation 2016*. Please refer to 'Sending your goods to Australia' on the Department of Agriculture, Fisheries and Forestry website.

Provision of required documentation

It is recommended that all required documentation accompanies each consignment. Required documentation must be presented to the Department of Agriculture, Fisheries and Forestry for assessment. Airfreight or mail shipments should have all required documentation securely attached to the outside of the package, and clearly marked "Attention Department of Agriculture, Fisheries and Forestry" Documentation may include the permit (or permit number), government certification and invoice.

If the product description on the permit varies from the identifying documentation provided, the goods will not be released from biosecurity control unless evidence is provided to the biosecurity officer that the permit covers the goods in the consignment.

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

Non-commodity cargo clearance

In addition to the conditions for the goods being imported, non-commodity biosecurity risks are 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.

Fees

Fees are payable to the Department of Agriculture, Fisheries and Forestry for certain services (see the *Biosecurity Charges Imposition (General) Regulation 2016*, Part 2 of Chapter 9 of the *Biosecurity Regulation 2016* and Part 3 of Chapter 11 of the *Biosecurity Act 2015*). Detail on how the department applies fees and levies may be found in the Charging guidelines.

Compliance with other regulatory provisions

Goods imported into Australia may be subject to regulatory requirements under other legislation. It is the permit holder's responsibility to identify and ensure they have complied with all requirements of any other regulatory agency or advisory body prior to and after importation.

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. Human fluids and tissues that are free from listed diseases

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

1.	Human fluids and tissues

1.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the import of human fluids and tissues only.

b. The goods must have been taken from persons not suspected to be infected with and not diagnosed with:

1. A Listed Human Disease. Listed Human Diseases are those that are listed under the *Biosecurity (Listed Human Diseases) Determination 2016*, which is published on the Federal Register of Legislation (the Listed Human Diseases are also published on the Department of Health and Aged Care's website); and/or
2. Monkeypox, and/or
3. Polio.

c. The goods must not be known to be infected with Listed Human Diseases, pathogens of animal biosecurity concern (as published on the Department of Agriculture, Fisheries and Forestry's website), monkeypox virus or poliovirus.

d. If the conditions above cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

e. The goods must not be known (or suspected) to be infected with prion proteins (whether protease resistant or not, including PRNP, PrPc and PrPsc) or any other agent of transmissible spongiform encephalopathy from any other species.

f. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the specimens were only taken from persons not suspected to be infected with and not diagnosed with a Listed Human Disease, monkeypox or polio.

2. A statement that the specimens are not known to be infected with any Listed Human Diseases, pathogen of animal biosecurity concern, monkeypox virus or poliovirus.

AND

ii. **Prion freedom**

3. A statement that the specimens are not known (or suspected) to be infected with prion proteins (whether protease resistant or not, including PRNP, PrPc and PrPsc) or any other transmissible spongiform encephalopathy from any species.

Related Information:

- Website: Listed Human Diseases
- Website: Pathogens of animal biosecurity concern for biological products

Import conditions after arrival in Australian territory

g. 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.

It is the importer's 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.

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

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

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

Additional information

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.

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.

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,

Fisheries and Forestry 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. Animal fluids and tissues (excluding reproductive material) sourced from avians only

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

2.	Animal fluids and tissues (excl. viable reproductive material)

2.1. Biosecurity Pathway

a. **Source species and countries**

The goods must be fluids and tissues sourced from avians only, which resided in countries approved for avian fluids and tissues (as listed on the department's website) at the time of collection.

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are of <<*insert species of animal*>> origin only.
2. A statement that the goods have only been sourced from animal/s residing in <<*insert name/s of country/ies*>>.
3. A statement that the goods are not reproductive material.

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:
   3.1. the goods are not antisera, or
   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.
   [The declaration must indicate the option that applies].

c. If the above conditions cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50 kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

1. individually packaged in units of no greater than 20mL or 20g, or
2. urine only, and are individually packaged in units no greater than 500mL.

[The declaration must indicate the option that applies].

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.

These conditions do not permit:

1. culturing or isolating microorganisms and infectious agent.
2. the synthesis of replication-competent microorganisms, infectious agent or homologues.

It is the importer's 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.

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

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

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

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.

f. **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.

g. 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.

h. 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.

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

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

3.	Antibodies

3.1. Biosecurity Pathway

a. This import permit covers the requirements for the importation of antibodies purified and raised against multicellular organisms (excluding fungi and prion proteins from all organisms) or synthetic (non-biological) material only.

This import permit does not cover the requirements for the importation of antibodies which are suspended in animal products e.g. sera, albumin or supernatant fluid.

b. The antibodies may be conjugated to radioactive isotopes or to fluorescent proteins derived from multicellular animals and plants.

c. The antibodies may be conjugated with chemical compounds which are not nucleotides or amino acids, unless the compound is less than 10 amino acids in length.

d. The goods are individually packaged in units of no greater than 20mL or 20g.

e. Each product must be clearly identified as an antibody.

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 name of the antibody/ies and the name of the antigen/s the antibody is raised against.

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
5. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

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

It is the importer's 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.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

4. Antibodies produced in recombinant systems or raised against recombinant antigens (Standard Permit)

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

4.	Antibodies

4.1. Biosecurity Pathway

a. This import permit covers the requirements for the importation of purified antibodies that are either:

1. antibodies produced without an immune response using a recombinant DNA expression system; or
2. antibodies raised against antigens produced using a recombinant DNA expression system, excluding antigens produced using a recombinant DNA expression system encoding whole genome segments of any virus or viroid.

Import conditions prior to arrival in Australian territory

b. The antibodies must not be suspended in whole blood, sera, plasma or ascitic fluid.

c. The antibodies must not be raised against any prion (whether naturally occurring, chemically synthesized or recombinant protein) from any species.

d. The antibodies must be purified using either affinity purification or chromatographic purification methods.

e. The antibodies may be conjugated to a protein, other than prion protein, produced using a recombinant DNA expression system.

f. The antibodies may be conjugated to chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.

g. The goods are individually packaged in units of no greater than 20mL or 20g.

h. The goods must meet biosecurity requirements.

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:

1. The name of each antibody; and
2. The name of the antigen for each antibody; and
3. A statement that the antibody/ies were not raised against any prions (whether naturally-occurring, chemically-synthesized or recombinant protein); and
4. A statement that each antibody was purified using either affinity purification or chromatographic purification methods only; and
5. The following statement(s) where they apply:

   5.1. A statement that the antibody/ies are produced without an immune response using a recombinant DNA expression system; or
   5.2. A statement that the antibody/ies are raised against antigens produced using a recombinant DNA expression system, excluding antigens produced using a recombinant DNA expression system encoding whole genome segments of any virus or viroid.

i. **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
5. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

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

It is the importer's 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.

Additional information

j. **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.

k. 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.

l. 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.

5. Cell lines of laboratory animal, insect and human origin

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

5.	Cell lines and/or supernatant fluid

5.1. Biosecurity Pathway

a. The following conditions apply to cell lines and/or supernatant fluid from humans, guinea pigs, rats, mice, hamsters, rabbits, insects, and hybridomas of these species. These conditions do 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 (other than viral DNA which has been used to immortalise the cell line).

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

1. a statement that the cell line has shown no signs of contamination, including cytopathic effects, with adventitious infectious agents or microbial 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 or humans 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. **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@awe.gov.au or call 1800 900 090.

It is the importer's 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.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

6. Nucleic Acid Amplification (NAA) test kits

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

6.	Test kits

6.1. Biosecurity Pathway

These conditions allow for the import of:

1. Polymerase Chain Reaction (PCR) test kits.
2. Real-Time PCR or Quantitative PCR (qPCR) test kits.
3. Reverse Transcriptase PCR (RT-PCR) test kits.
4. Loop-Mediated Isothermal Amplification (LAMP) test kits.

Additional reagents, controls, calibrators etc. may also be imported:

1. when specifically designed for use with test kits eligible for import under these conditions.
2. where they can meet all import conditions.
3. whether or not they are imported in the same consignment (separate to the test kit) or in a separate consignment.

a. 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 goods are Nucleic Acid Amplification (NAA) test kits only (or individual components specifically designed for use with kits eligible for import under these conditions).
2. A statement that the goods contain nucleic acid up to 1000 nucleotides, enzymes and chemical buffers only.

Product name(s) of each kit and each reagent, control, calibrator etc. (if imported separately to the kit) must be included on the manufacturer's declaration.

b. The goods must be commercially manufactured and packaged.

c. The goods are for *in vitro* use only.

The following end uses are not permitted:

1. Culturing or isolating disease agents.
2. The synthesis of replication-competent disease agents or homologues.
3. Direct or indirect exposure to animals (including laboratory animals) or plants.

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. Any regulatory requirements of the Therapeutic Goods Administration (TGA).
5. Any regulatory requirements of the Australian Pesticide and Veterinary Medicines Authority (APVMA).
6. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

7. Diagnostic test kits excluding those testing for Listed Human Diseases and zoonotic diseases

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

7.	Test kits

7.1. Biosecurity Pathway

These conditions allow for the import of diagnostic test kits testing for human conditions including:

1. disease agents, excluding zoonotic diseases of biosecurity concern (Appendix 1) and Listed Human Diseases. Listed Human Diseases are those that are listed under the *Biosecurity (Listed Human Diseases) Determination 2016*, which is published on the Federal Register of Legislation (the Listed Human Diseases are also published on the Department of Health's website).
2. haematology tests
3. hormone tests, including pregnancy tests
4. drug tests
5. genetic tests
6. allergy test kits.

Additional reagents, controls, calibrators etc. may also be imported:

1. when specifically designed for use with diagnostic test kits eligible for import under these conditions.
2. where they can meet all import conditions.
3. whether or not they are imported in the same consignment (separate to the diagnostic test kit) or in a separate consignment.

a. 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:
   1.1. The goods are diagnostic test kits (or individual components specifically designed for use with kits eligible for import under these conditions) testing human conditions only.
   1.2. All components derived from disease agents are incapable of replicating.
   1.3. The goods do not test for Listed Human Diseases (as published on the Department of Health's website) or zoonotic diseases of biosecurity concern (Appendix 1).
   1.4. The goods do not contain Listed Human Diseases (as published on the Department of Health's website) or zoonotic diseases of biosecurity concern (Appendix 1)(live, live attenuated or inactivated) or their derivatives (e.g. antigens).
   1.5. The goods do not contain any components raised against Listed Human Diseases (as published on the Department of Health's website) or zoonotic diseases of biosecurity concern (Appendix 1) (e.g. antibodies).

2. A statement that all animal derived material contained in these diagnostic test kit(s) is in volumes of no greater than 20ml or 20g per individually packaged unit.
   Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained must not be greater than 20ml or 20g.

Product name(s) of each kit and each reagent, control, calibrator etc. (if imported separately to the kit) must be included on the manufacturer's declaration.

b. The goods must be commercially manufactured and packaged.

c. The goods are for:

1. *in vitro* use, or
2. allergy testing for external use on humans only (e.g. skin prick tests).

The following end uses are not permitted:

1. The isolation of disease agents from the imported material.
2. The synthesis of replication-competent disease agents or homologues from the imported material.
3. Direct or indirect exposure to animals (excluding allergy testing of humans) or plants.

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. Any regulatory requirements of the Therapeutic Goods Administration (TGA).
5. Any regulatory requirements of the Australian Pesticide and Veterinary Medicines Authority (APVMA).
6. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

8. Test kits not testing for disease agents

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

8.	Test kits

8.1. Biosecurity Pathway

These conditions allow for the import of test kits testing for human, veterinary and environmental conditions including:

1. haematology tests,
2. hormone tests, including pregnancy tests etc.,
3. drug tests,
4. chemical tests,
5. genetic tests,
6. environmental test kits, including soil test kits,
7. allergy test kits for use on humans only.

Additional reagents, controls, calibrators etc. may also be imported:

1. when specifically designed for use with test kits eligible for import under these conditions.
2. where they can meet all import conditions.
3. whether or not they are imported in the same consignment (separate to the test kit) or in a separate consignment.

a. 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 goods are test kits (or individual components specifically designed for use with kits eligible for import under these conditions), which:
   1.1. do not test for disease agents.
   1.2. do not contain disease agents (live, live attenuated, or inactivated) or their derivatives (e.g. antigens).
   1.3. do not contain any components raised against disease agents (e.g. antibodies).
2. A statement that all animal derived material contained in these test kit(s) is in volumes of no greater than 20ml or 20g per individually packaged unit.
   Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained within must not be greater than 20ml or 20g.

Product name(s) of each kit and each reagent, control, calibrator etc. (if imported separately to the kit) must be included on the manufacturer's declaration.

b. The goods must be commercially manufactured and packaged.

c. The goods are for:

1. *in vitro* use, or

2. allergy testing for external use on humans only (e.g. skin prick tests).

The following end uses are not permitted:

1. The isolation of disease agents from the imported material.
2. The synthesis of replication-competent disease agents or homologues from the imported material.
3. Direct or indirect exposure to animals (excluding allergy testing of humans) or plants.

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. Any regulatory requirements of the Therapeutic Goods Administration (TGA).
5. Any regulatory requirements of the Australian Pesticide and Veterinary Medicines Authority (APVMA).
6. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

9. Genetic material from multicellular organisms (Including listed vectors) and vectors

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

9.	Genetic material

9.1. Biosecurity Pathway

a. 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, fungi or prions from any species) 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 and infectious agents (including prions).
2. Genetic material derived from plants.
3. Genetic material derived from fungi.

b. The goods must meet biosecurity requirements.

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:

Evidence:

1. that the genetic material has been highly purified and is unable to replicate; and
2. the name of the source multicellular organism; and
3. the name of the cloning vector (if applicable).

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@awe.gov.au or call 1800 900 090.

It is the importer's 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.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

10. Genetic material, purified and derived from microorganisms and viruses (excluding listed species)

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

10.	Genetic material

10.1. Biosecurity Pathway

a. These conditions allow for the import of genetic material, purified and derived from microorganisms and viruses (excluding listed species) only.

b. The goods must be clearly labelled with the name of the source microorganism or infectious agent.

c. The genetic material must not be derived from microorganisms and infectious agents in the list of microorganisms and infectious agents of significant biosecurity concern (Appendix 2).

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

A declaration stating:

1. that the genetic material has been highly purified and is unable to replicate, and
2. the name (genus and species) of the source microorganism or infectious agent.

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
5. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

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

It is the importer's 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.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

11. Standard laboratory microorganisms and infectious agents (and derivatives)

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

11.	Microorganisms (including viruses)

Some products may require specialised storage and/or handling.

11.1. Biosecurity Pathway

a. The product must be on the list of standard laboratory microorganisms and infectious agents.

Please refer to the standard laboratory microorganisms and infectious agents (Appendix 3) list.

b. Derivatives must be primary derivatives i.e. components that have been directly isolated and purified from a pure culture of the microorganism. Secondary derivatives i.e. components of the microorganism that have undergone passage or inoculation into a second organism e.g. antibodies, are not permitted under these import conditions.

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

c. Importation of the following is permitted:

1. Nucleic acid sequences directly isolated from or identical to any standard laboratory microorganisms and infectious agents (Appendix 3) may also be imported in purified standard laboratory cloning vectors and expression vectors as described in point 3. below, or as linear nucleic acid fragments.
2. The microorganisms listed may also contain standard laboratory cloning vectors and expression vectors as listed and as described in point 3. below. These standard cloning and expression vectors may include nucleic acid from the organisms listed below in addition to the nucleic acid backbone:
   2.1. Multicellular organisms (excluding plants or fungi), or
   2.2. any microorganism/s and viruses in the standard laboratory microorganisms and infectious agents list
3. Permitted purified standard laboratory cloning and expression vectors are:
   3.1. Plasmids, cosmids, yeast and bacterial artificial chromosomes, 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
   3.2. Human immunodeficiency virus (HIV) vectors, bacteriophages lambda, lambdoid and Ff, polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV). No other viral vectors are permitted; and
   3.3. *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors.

d. Microorganisms and infectious agents may be imported on a non-biological matrix (e.g. biological indicators, spore strips).

e. Each culture, derivative, sequence or vector 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 or the source microorganism of derivatives, sequences and vectors.

Cultures must be pure cultures 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.

Derivatives of microorganisms must be primary derivatives only and labelled with the scientific name of the source organism as it appears on the import permit including genus, species and any other criteria e.g. subspecies, strain, biotype, serotype, pathovar, variety etc. Product numbers or codes matching an invoice or inventory list are acceptable for goods in small vials.

f. **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@awe.gov.au or call 1800 900 090.

It is the importer's 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.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

12. Purified laboratory material, laboratory reagents, toxins and venoms

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

12. Purified laboratory reagents, toxins and venoms

12.1. Biosecurity Pathway

a. These conditions allow for the import of the following purified goods only:

1. albumins (including bovine serum albumin (BSA))
2. antibiotics (e.g. antibiotic sensitivity discs)
3. enzymes
4. enzyme inhibitors
5. growth factors
6. hormones
7. laboratory material derived from a fermentation process
8. toxins
9. venoms
10. co-factors
11. lipids (includes fats, waxes, sterols, glycerides, phospholipids and their derivatives)
12. other proteins (including derivatives e.g. peptides) not listed under any of the categories 1-9 above, excluding:
    12.1. prions (derived from an organism, recombinant protein, or synthetic)
    12.2. antibodies
    12.3. proteins (including derivatives e.g. peptides) derived from:
    12.3.1. Pathogens of animal biosecurity concern for biological products, as published on the department's website
    12.3.2. Disease agents causing Listed Human Diseases, as published on the Department of Health's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.

b. The goods must have been purified using a validated method and must not be contaminated with an infectious agent.

c. The goods must not be, or contain, live or infectious material, or any genetic material.

d. The goods must be individually packaged in units of no greater than 20mL or 20g.

e. The goods must meet biosecurity requirements.

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:

1. A description of the goods.
2. A statement that the goods have been purified using a validated method that removes/inactivates all infectious material.
3. A statement that the goods do not contain live or infectious material, or genetic material.
4. Evidence that the goods are in quantities of no greater than 20ml or 20g for each individually packaged unit.

5. For import of other proteins (including derivatives e.g. peptides) that are not listed under another category above (e.g. albumins, enzymes) and that are not prions, antibodies or proteins derived from a pathogen of animal biosecurity concern for biological products or a disease agent causing a Listed Human Disease, the below must be also included:
   A statement that the goods are not prions or antibodies, and were not derived from a pathogen of animal biosecurity concern for biological products (as published on the Department of Agriculture, Water and the Environment's website) or a disease agent causing a Listed Human Disease (as published on the Department of Health's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016).*

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
5. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

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

It is the importer's 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.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

13. Animal fluids and tissues (excl. viable reproductive material) sourced from captive primates only

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

13.	Animal fluids and tissues (excl. viable reproductive material)

13.1. Biosecurity Pathway

a. **Source species**

The goods must be fluids and tissues sourced from captive primates that are held within laboratory or zoological facilities only.

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods were obtained from primates held within a laboratory or zoological facility only.
2. A statement that the goods:

2.1. are not reproductive material, or

2.2. the reproductive material is:
2.2.1. non-viable,
2.2.2. is transported at room temperature, and
2.2.3. is not intended for use in artificial insemination (AI) or assisted reproductive treatment (ART).

[The declaration must indicate the option that applies.]

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:
3.1. the goods are not antisera, or
3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.
[The declaration must indicate the option that applies].

c. If the above conditions cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50 kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

1. individually packaged in units of no greater than 20mL or 20g, or
2. urine only, and are individually packaged in units no greater than 500mL.

[The declaration must indicate the option that applies].

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.

These conditions do not permit:

1. culturing or isolating microorganisms and infectious agent.
2. the synthesis of replication-competent microorganisms, infectious agent or homologues.

It is the importer's 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.

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

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

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

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.

f. **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.

g. 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.

h. 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.

14. Animal fluids and tissues (excluding reproductive material) sourced from ovines and caprines only

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

14.	Animal fluids and tissues (excl. viable reproductive material)

14.1. Biosecurity Pathway

a. **Source species and countries**

The goods must be fluids and tissues sourced from ovines and/or caprines only, which resided in countries approved for ovine and caprine fluids and tissues (as listed on the department's website) at the time of collection.

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are of <<*insert species of animal*>> origin only.
2. A statement that the goods have only been sourced from animal/s residing in <<*insert name/s of country/ies*>>.
3. A statement that the goods are not reproductive material.

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:
   3.1. the goods are not antisera, or
   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.
   [The declaration must indicate the option that applies].

c. If the above conditions cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50 kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

1. individually packaged in units of no greater than 20mL or 20g, or
2. urine only, and are individually packaged in units no greater than 500mL.

[The declaration must indicate the option that applies].

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.

These conditions do not permit:

1. culturing or isolating microorganisms and infectious agent.
2. the synthesis of replication-competent microorganisms, infectious agent or homologues.

It is the importer's 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.

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

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

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

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.

f. **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.

g. 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.

h. 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.

15. Animal fluids and tissues (excluding reproductive material) sourced from bovines only

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

15.	Animal fluids and tissues (excl. viable reproductive material)

15.1. Biosecurity Pathway

a. **Source species and countries**

The goods must be fluids and tissues sourced from bovines only, which resided in countries approved for bovine fluids and tissues (as listed on the department's website) at the time of collection.

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are of <<*insert species of animal*>> origin only.
2. A statement that the goods have only been sourced from animal/s residing in <<*insert name/s of country/ies*>>.
3. A statement that the goods are not reproductive material.

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:
   3.1. the goods are not antisera, or
   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.
   [The declaration must indicate the option that applies].

c. If the above conditions cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50 kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

1. individually packaged in units of no greater than 20mL or 20g, or
2. urine only, and are individually packaged in units no greater than 500mL.

[The declaration must indicate the option that applies].

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.

These conditions do not permit:

1. culturing or isolating microorganisms and infectious agent.
2. the synthesis of replication-competent microorganisms, infectious agent or homologues.

It is the importer's 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.

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

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

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

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.

f. **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.

g. 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.

h. 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.

16. Animal fluids and tissues (excluding reproductive material) sourced from cervines (deer) only

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

16.	Animal fluids and tissues (excl. viable reproductive material)

16.1. Biosecurity Pathway

a. **Source species and countries**

The goods must be fluids and tissues sourced from cervines only, which resided in countries approved for cervine fluids and tissues (as listed on the department's website) at the time of collection.

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are of <<*insert species of animal*>> origin only.
2. A statement that the goods have only been sourced from animal/s residing in <<*insert name/s of country/ies*>>.
3. A statement that the goods are not reproductive material.

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:
   3.1. the goods are not antisera, or
   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.
   [The declaration must indicate the option that applies].

c. If the above conditions cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50 kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

1. individually packaged in units of no greater than 20mL or 20g, or
2. urine only, and are individually packaged in units no greater than 500mL.

[The declaration must indicate the option that applies].

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.

These conditions do not permit:

1. culturing or isolating microorganisms and infectious agent.
2. the synthesis of replication-competent microorganisms, infectious agent or homologues.

It is the importer's 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.

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

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

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

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.

f. **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.

g. 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.

h. 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.

17. Animal fluids and tissues (excluding reproductive material) sourced from camelids only

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

17.	Animal fluids and tissues (excl. viable reproductive material)

17.1. Biosecurity Pathway

a. **Source species and countries**

The goods must be fluids and tissues sourced from camelids only, which resided in countries approved for camelid fluids and tissues (as listed on the department's website) at the time of collection.

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are of <<*insert species of animal*>> origin only.
2. A statement that the goods have only been sourced from animal/s residing in <<*insert name/s of country/ies*>>.
3. A statement that the goods are not reproductive material.

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:
   3.1. the goods are not antisera, or
   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.
   [The declaration must indicate the option that applies].

c. If the above conditions cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50 kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

1. individually packaged in units of no greater than 20mL or 20g, or
2. urine only, and are individually packaged in units no greater than 500mL.

[The declaration must indicate the option that applies].

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.

These conditions do not permit:

1. culturing or isolating microorganisms and infectious agent.
2. the synthesis of replication-competent microorganisms, infectious agent or homologues.

It is the importer's 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.

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

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

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

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.

f. **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.

g. 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.

h. 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.

18. Animal fluids and tissues (excluding reproductive material) sourced from suids (porcines) only

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

18.	Animal fluids and tissues (excl. viable reproductive material)

18.1. Biosecurity Pathway

a. **Source species and countries**

The goods must be fluids and tissues sourced from suids (porcines) only, which resided in countries approved for suid fluids and tissues (as listed on the department's website) at the time of collection.

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are of <<*insert species of animal*>> origin only.
2. A statement that the goods have only been sourced from animal/s residing in <<*insert name/s of country/ies*>>.
3. A statement that the goods are not reproductive material.

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:
   3.1. the goods are not antisera, or
   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.
   [The declaration must indicate the option that applies].

c. If the above conditions cannot be met, the goods must be treated with ionising radiation to a level that achieves a minimum absorbed dose of 50 kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

1. individually packaged in units of no greater than 20mL or 20g, or
2. urine only, and are individually packaged in units no greater than 500mL.

[The declaration must indicate the option that applies].

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.

These conditions do not permit:

1. culturing or isolating microorganisms and infectious agent.
2. the synthesis of replication-competent microorganisms, infectious agent or homologues.

It is the importer's 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.

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

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

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

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.

f. **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.

g. 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.

h. 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.

19. Cell lines from non-laboratory animals

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

19.	Cell lines and/or supernatant fluid

19.1. Biosecurity Pathway

a. The following conditions apply to cell lines and/or supernatant fluid derived from all animal species **excluding** guinea pigs, rats, mice, hamsters, rabbits, insects and hybridomas of these species. The import permit does not allow for importation of human cell lines and 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 (other than viral DNA which has been used to immortalise the cell line).

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

1. a statement that the cell line has shown no signs of contamination, including cytopathic effects, with adventitious infectious agents or microbial 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 or humans 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. Additional conditions 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 or Supplier'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, rinderpest and lumpy skin disease, 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 or the cell line/media has been tested and found free of these pathogens.

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@awe.gov.au or call 1800 900 090.

It is the importer's 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.

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, Water and the Environment 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 Non-Commodity Cargo Clearance BICON case for further information.

Appendix 1: Zoonotic diseases of biosecurity concern

Viruses and Prions:

1. Avian influenza (avian influenza virus).
2. Equine encephalomyelitis (Eastern, Venezuelan and Western equine encephalomyelitis viruses).
3. Foot and mouth disease (foot and mouth disease virus).
4. Japanese encephalitis (Japanese encephalitis virus).
5. Hantaan virus (Korean haemorrhagic fever virus).
6. Louping ill (also known as Russian spring summer encephalitis, Central European encephalitis, caused by Louping ill virus).
7. Lymphocytic choriomeningitis (Lymphocytic choriomeningitis virus).
8. Newcastle disease (Newcastle disease virus).
9. Nipah virus encephalitis (Nipah virus).
10. Rift Valley fever (Rift Valley fever virus).
11. St Louis Encephalitis (St Louis Encephalitis virus).
12. Swine influenza (swine influenza virus).
13. Transmissible spongiform encephalopathy (Bovine spongiform encephalopathy, scrapie, variant Creutzfeldt-Jakob disease, prion protein).
14. Vesicular stomatitis (Vesicular stomatitis virus).
15. West Nile fever (West Nile virus).

Bacteria and fungi:

1. Anthrax (*Bacillus anthracis*).
2. Bovine tuberculosis (*Mycobacterium bovis*).
3. Brucellosis (*Brucellaabortus, B. canis, B melitensis*).
4. Enzootic abortion of ewes (*Chlamydophila abortus*).
5. Epizootic lymphangitis or histoplamosis (*Histoplasma capsulatum var. farciminosum*).
6. Glanders *(Burkholderia mallei*, formerly *Pseudomonas mallei*).
7. Salmonellosis (*Salmonella Abortusovis*, *Salmonella Enteritidis*, *Salmonella Gallinarum*, *Salmonella Pullorum*).
8. Tularemia (*Francisella tularensis*).

Appendix 2: Microorganisms and infectious agents of significant biosecurity concern

1. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).
2. Microorganisms and infectious agents associated with Listed Human Diseases. Listed Human Diseases are those that are listed under the *Biosecurity (Listed Human Diseases) Determination 2016*, which is published on the Federal Register of Legislation (the Listed Human Diseases are also published on the Department of Health's website).
3. Foot and mouth disease virus
4. African horse sickness virus
5. Peste des petits ruminants virus
6. Ovine and caprine pox virus
7. Pulmonary adenomatosis virus
8. Swine vesicular disease virus
9. African swine fever virus
10. Classical swine fever virus
11. Avian influenza virus
12. Newcastle disease virus.

Appendix 3: List: Standard laboratory microorganisms and infectious agents

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

Achromobacter spp.	*Acidianus spp.*	*Acidiphilium spp.*	*Acidithiobacillus spp.*
Acremonium cellulolyticus	*Actinomadura malachitica*	*Actinomadura viridis*	*Actinomyces rectiverticillatus*
Adeno-associated virus	*Aeromonas hydrophila*	*Alcaligenes denitrificans*	*Alicyclobacillus spp.*
Ampelomyces quisqualis	*Anabaena cylindrica*	*Anaerobacter polyendosporus*	*Aneurinibacillus migulanus (formerly Bacillus migulanus)*
Aquifex spp.	*Arthrobacter picolinophilus*	*Arthrobacter spp.*	*Aspergillus spp.*
Azorhizobium caulinodans	*Azotobacter spp.*	*Bacillus aminoglucosidicus*	*Bacillus atrophaeus (formerly Bacillus subtilis var. niger)*
Bacillus brevis syn. Brevibacillus brevis	*Bacillus cereus excluding Biovar anthracis*	*Bacillus fluorescens putidus*	*Bacillus geniculatus*
Bacillus ginsengihumi	*Bacillus licheniformis*	*Bacillus megaterium (excluding pv. cerealis)*	*Bacillus mesentericus*
Bacillus methylotrophicus	*Bacillus mojavensis*	*Bacillus pasteurii*	*Bacillus pumilus syn. Bacillus mesentericus, Bacillus aminoglucosidicus*
Bacillus putidus	*Bacillus simplex*	*Bacillus sphaericus*	*Bacillus stearothermophilus*
Bacillus subtilis	*Bacillus thuringiensis*	*Bacteroides spp.*	*Bartonella spp.*
Beauveria bassiana	*Bordetella spp.*	*Botryococcus spp.*	*Brachyspira spp.*
Brevibacillus spp. (excluding B. laterosporus)	*Burkholderia pseudomallei*	*Campylobacter spp.*	*Caulobacter spp.*
Chlamydia trachomatis	*Chlamydophila pneumonia*	*Chlorella spp.*	*Chryseobacterium spp. (excluding C. scophthalmum)*
Cicinnobolus cesatti	*Citrobacter spp.*	*Clostridium spp.*	*Comamonas acidovorans*

Corynebacterium spp. (excluding C. pseudotuberculosis)	*Cronobacter spp.*	*Cryptococcus spp.*	*Cryptomonas spp.*
Cryptosporidium spp.	*Dehalobacter spp.*	*Dehalococcoides spp.*	*Dehalogenimonas spp.*
Delftia acidovorans	*Desulfobacter spp.*	*Desulfovibrio spp.*	*Ensifer adhaerens*
Ensifer meliloti	*Entamoeba spp.*	*Enterobacter asburiae*	*Enterobacter spp.*
Enterococcus spp.	*Enterovirus (human origin only, and excluding swine vesicular disease virus and human enterovirus C)*	*Entomophthora anisopliae*	*Erwinia tasmaniensis*
Escherichia spp.	*Ferroplasma spp.*	*Fusarium venenatum*	*Geobacillus spp.*
Geobacter spp.	*Giardia spp.*	*Gigaspora margarita*	*Gliocadium catenalatum*
Haemophilus spp.	*Human Adenovirus Types 1-51*	*Human coxsackieviruses 1-24*	*Human echovirus 1-33*
Human hepatitis virus A, B, C, D, E, G &TTV	*Human Herpes virus 1-8 (includes Herpes simplex virus 1 and 2, Varicella zoster, Epstein-Barr virus and Cytomegalovirus)*	*Human immunodeficiency virus (HIV)*	*Human noroviruses*
Human papilloma virus	*Human respiratory syncytial virus*	*Human rhinovirus*	*Isochrysis galbana*
Klebsiella spp.	*Legionella spp.*	*Leptospira copenhageni (Leptospira interrogans serovar Copenhageni)*	*Leptospira gripptotyphosa (Leptospira interrogans serovar Gripptotyphosa)*
Leptospira hardjobovis (Leptospira borgpetersenii serovar hardjo-bovis)	*Leptospira icterohaemorrhagiae (Leptospira interrogans serovar Icterohaemorrhagiae)*	*Leptospira pomona (Leptospira interrogans serovar Pomona)*	*Leptospirillum spp.*
Listeria spp.	*Magnetospirillum spp. (formerly Aquaspirillum spp.)*	*Metapneumovirus (human)*	*Metarhizium acridum*
Metarhizium anisopliae var. anisopliae	*Methanococcus spp.*	*Microtetraspora viridis*	*Moraxella spp. (includes subgen. Branhamella and subgen. Moraxella) (excluding M. anatipestifer)*

Morganella spp.	*Murine cytomegalovirus (MCMV)*	*Murine leukaemia virus*	*Mycobacterium spp. (excluding M. bovis and M. caprae)*
Mycoplasma pneumoniae	*Nannochloropsis spp.*	*Neisseria spp.*	*Nippostrongylus brasiliensis*
Nocardia calcarea	*Ochrobactrum anthropi*	*Paenarthrobacter spp.*	*Paenibacillus alvei*
Paenibacillus brasiliensis	*Parainfluenza virus (human)*	*Pediococcus spp.*	*Penicillium chrysogenum*
Penicillium oxalicum	*Penicillium velutinum*	*Pleomorphomonas oryzae*	*Porphyromonas spp.*
Pristionchus americanus	*Pristionchus maupasi*	*Pristionchus pacificus*	*Proteus spp.*
Providencia spp.	*Pseudomonas acidovorans*	*Pseudomonas aeruginosa*	*Pseudomonas antarctica*
Pseudomonas citronellolis	*Pseudomonas convexa*	*Pseudomonas eisenbergii*	*Pseudomonas fluorescens (excluding biovar II)*
Pseudomonas geniculata	*Pseudomonas incognita*	*Pseudomonas monteilii*	*Pseudomonas ovalis*
Pseudomonas putida	*Pseudomonas rugosa*	*Pseudomonas striata*	*Rhabditis myriophila*
Rhizobium meliloti	*Rhodobacter spp.*	*Rhodococcus spp.*	*Roseomonas spp.*
Rubella virus	*Rubrivivax spp.*	*Saccharopolyspora spinosa*	*Saccharopolyspora spp.*
Salmonella Adelaide (Salmonella enterica subsp. enterica serovar Adelaide)	*Salmonella Agona (Salmonella enterica subsp. enterica serovar Agona)*	*Salmonella Derby (Salmonella enterica subsp. enterica serovar Derby)*	*Salmonella Salford (Salmonella enterica subsp. enterica serovar Salford)*
Salmonella Senftenburg (Salmonella enterica subsp. enterica serovar Senftenberg)	*Scutellospora dipurpurescens*	*Serratia spp.*	*Shewanella spp. (excluding Shewanella marisflavi)*
Shigella spp.	*Sindbis virus*	*Sinorhizobium adhaerens*	*Sinorhizobium meliloti*
Sporosarcina pasteurii	*Staphylococcus spp.*	*Stenotrophomonas spp.*	*Streptococcus spp.*
Streptomyces rectiverticillatus	*Streptoverticillium rectiverticillatum*	*Suillus granulatus*	*Sulfobacillus spp.*
Sulfolobus spp.	*Sulfurisphaera spp.*	*Tetrahymena spp.*	*Thermus spp.*
Thiobacillus spp.	*Toxoplasma spp.*	*Tritirachium shiotae*	*Tritirachium shiotae*

Vaccinia virus (cow pox)	*Vibrio alginolyticus*	*Vibrio cholerae (excluding serotype 01 and serotype 0139)*	*Vibrio parahaemolyticus (excluding VPAHPND strains with plasmid coding for Pir toxin homologues)*
Vibrio vulnificus (excluding biovar II)	*Wolinella succinogens*	*Xanthobacter spp.*	*Yersinia enterocolitica*

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