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: 0010414455

Valid for: multiple consignments between 13 June 2025 and 13 June 2030

This permit is issued to: MACQUARIE UNIVERSITY
Macquarie University
14 Eastern Road
MACQUARIE UNIVERSITY NSW 2109
AUSTRALIA

Attention: Mrs Negin Farzadian

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 not known to be infected	Page 7
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:	Purified antibodies raised against inorganic or multicellular antigens (Standard Permit)	Page 12
4. Animal fluids and tissues (excl. viable reproductive material)		

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

Sarah Jeffress
Subdelegate of the Director of Biosecurity Date: 16 April 2025

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 14

5. 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 17

6. 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 20

7. 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:	Salmonidae (salmon) fish fluids and tissues (excluding reproductive material)	Page 23

8. 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) from species, other than those excluded	Page 25

9. 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:	Purified antibodies raised against disease agents, including microorganisms (Standard Permit)	Page 28

10. Antibodies		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Antibodies produced in recombinant systems or raised against recombinant antigens (Standard Permit)	Page 30

11. Antigens		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Antigens that are purified and derived from multicellular organisms or synthetic material	Page 33

12. 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 35
13. 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 37
14. Culture media (no greater than 20ml or 20g animal derived 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:	Culture media containing no greater than 20ml or 20g animal derived material	Page 40
15. 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 derived from multicellular organisms (Standard Permit)	Page 42
16. 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 derived from or homologous to sequences from disease agents (Standard Permit)	Page 44
17. 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:	Standard laboratory vectors for routine scientific purposes	Page 46
18. 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:	Standard laboratory vectors for nucleic acid sequencing	Page 51
19. 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 54
20. Prepared media including pre-poured plates, swabs and vials		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	

Country of origin:	Various countries	
Permit Conditions:	Prepared culture media including pre-poured plates, swabs and vials no greater than 50 mL or 50 g	Page 57

21. 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 59

22. Soil and water samples		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Potable water samples sourced from a conveyance for laboratory studies	Page 62

23. Soil and water samples		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Sediment and related samples from the sea or ocean floor	Page 64

24. Soil and water samples		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Environmental samples for laboratory analysis, culture and isolation not permitted	Page 67

25. 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 71

26. 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 74

27. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Test kits testing for disease agents excluding pathogens of biosecurity concern (Standard)	
Permit Conditions:	Test kits for disease agents excl. Listed Human Diseases and Pathogens of Animal Biosecurity Concern	Page 77

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 not known to be infected

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 be sourced from humans with no clinical signs of infectious disease at the time of collection.

c. The goods must not have been deliberately infected with a disease agent.

d. The goods must not be known (or suspected) to be infected with disease causing prion proteins (whether protease resistant or not).

e. 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**

A statement that the specimens:

1. were not sourced from humans with clinical signs of infectious disease
2. are not known to be infected with any disease agent.

AND

ii. **Prion freedom**

3. A statement that the specimens are not known (or suspected) to be infected with disease causing prion proteins (whether protease resistant or not).

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

OR

The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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

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

h. 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.

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.

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

Import conditions prior to arrival in Australian territory

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**

A statement that the goods:

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

AND

ii. **Animal Health**

A statement that:

1. The goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. The goods have not been deliberately infected with a disease agent.
3. 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. 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].

Import conditions after arrival in Australian territory

d. 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.

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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. Purified antibodies raised against inorganic or multicellular antigens (Standard Permit)

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

3. Antibodies

3.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the import of purified antibodies raised against either:

1. multicellular organisms (or parts of multicellular organisms), excluding fungi, that are not genetically-modified and have not been deliberately infected with a disease agent*, and are not known to be infected with a disease agent*,
2. inorganic or chemically-synthesised material, excluding material encoding whole genome segments of any virus or viroid. Inorganic means not consisting of or deriving from any living matter, virus or viroid.

*Disease agent includes but is not limited to microorganism, parasite, virus, prion, plasmid or viroid.

b. The antibodies must not be suspended in whole blood, sera, plasma, ascitic fluid or culture supernatant 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 may be conjugated to chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.

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

f. 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 each antibody is raised against (including the common and/or scientific name of the multicellular organism, or name of the non-biological/chemically-synthesized material); and
3. A statement that the antibody/ies are raised against:

   3.1. multicellular organisms (or parts of multicellular organisms), excluding fungi, that are not genetically-modified and have not been deliberately infected with a disease agent, and are not known to be infected with a disease agent; or

   3.2. inorganic or chemically-synthesised material, excluding material encoding whole genome segments of any virus or viroid; and
4. A statement that the antibody/ies were not raised against any prions (whether naturally-occurring, chemically-synthesized or recombinant protein)

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are

guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.

2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

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.

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

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

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

4.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

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**

A statement that the goods:

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

AND

ii. **Animal Health**

A statement that:

1. The goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. The goods have not been deliberately infected with a disease agent.
3. 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].

Import conditions after arrival in Australian territory

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**

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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.

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

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

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

5.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

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**

A statement that the goods:

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

AND

ii. **Animal Health**

A statement that:

1. The goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. The goods have not been deliberately infected with a disease agent.
3. 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. 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].

Import conditions after arrival in Australian territory

d. 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.

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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.

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

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

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

6.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

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**

A statement that the goods:

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

AND

ii. **Animal Health**

A statement that:

1. The goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. The goods have not been deliberately infected with a disease agent.
3. 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. 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].

Import conditions after arrival in Australian territory

d. 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.

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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.

7. Salmonidae (salmon) fish fluids and tissues (excluding reproductive material)

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

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

7.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. **Source species**

The goods must be fluids and tissues sourced from Salmonidae (salmon) species (Appendix 1) 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**

A statement that the goods:

1. are of Salmonidae (salmon) origin only
2. are not reproductive material.

AND

ii. **Animal Health**

A statement that:

1. The goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. The goods have not been deliberately infected with a disease agent.
3. 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. 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].

Import conditions after arrival in Australian territory

d. 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.

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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.

8. Animal fluids and tissues (excluding reproductive material) from species, other than those excluded

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

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

8.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. **Sourcing**
The goods must be animal fluids and tissues only.

The goods must not be reproductive material.

b. The goods must not be sourced from: avians, bovines, camelids, caprines, cervines, equines, giraffids, ovines, prawns, primates, suids (porcines) or Salmonidae fish.

Animal does not include a human or a part of a human. This permit excludes goods containing human derived material.

c. **Animal Health**
The goods must not be sourced from animals with signs of infectious disease at the time of collection.

The goods must not have been deliberately infected with a disease agent other than those listed below.

Antisera may only be raised against:

1. synthetic material, or
2. antigens derived from multicellular organisms, or
3. approved starter cultures, or
4. standard laboratory microorganisms (including viruses) list.

d. **Packaging**
The goods must be imported in quantities of no greater than:

1. 20mL or 20g for each individually packaged unit, or
2. for urine only, 500mL or 500g for each individually packaged unit.

e. 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**
A statement that the goods:

1. are animal fluids and tissues only
2. have not been soured from avians, bovines, camelids, caprines, cervines, equines, giraffids, ovines, prawns, primates, suids (porcines) or Salmonidae fish
3. are not reproductive material.

AND

ii. **Animal Health**

A statement that:

1. The goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. The goods have not been deliberately infected with a disease agent.
3. 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].

f. 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].

Import conditions after arrival in Australian territory

g. 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.

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

i. **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.

j. 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.

k. 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. Purified antibodies raised against disease agents, including microorganisms (Standard Permit)

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

9.	Antibodies

9.1. Biosecurity Pathway

a. This import permit covers the requirements for the importation of purified antibodies that are raised against disease agents (or antigens that are parts of or produced by disease agents), excluding:

1. Pathogens of animal biosecurity concern for biological products, as published on the Department of Agriculture, Fisheries and Forestry's website; and
2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.

*Disease agent includes but is not limited to microorganism, parasite, virus, prion, plasmid 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 chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.

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

g. 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 each antibody is raised against (including the common and/or scientific name of the disease agent); and
3. A statement that the antibody/ies were not raised against any prions (naturally-occurring, chemically-synthesized or recombinant proteins); and
4. A statement that the antibody/ies were purified using either affinity purification or chromatographic purification methods; and
5. A statement that the antibody/ies were not raised against antigens consisting of, or produced by, a pathogen of animal biosecurity concern for biological products (as published on the Department of Agriculture, Fisheries and Forestry website) or a disease agent causing a Listed Human Disease (as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation).

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

i. **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.

j. 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.

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

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

10.	Antibodies

10.1. Biosecurity Pathway

a. This import permit covers the requirements for the importation of 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.

> A **genome segment** is defined as a complete frame of an organism's genome that encodes all or a functional part of the organism's genome, including:
>
> - The whole genome of non-segmented viruses or prokaryotes; or
> - An individual fragment of nucleic acid among two or more fragments that together comprise the complete viral genome of segmented viruses; or
> - A chromosome of a eukaryotic organism; or
> - A transposon or repetitive DNA sequence that can change its position within a genome; or
> - Entire native plasmids that are not artificially constructed.

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**

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

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.

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.

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, Fisheries and Forestry 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.

11. Antigens that are purified and derived from multicellular organisms or synthetic material

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

11. Antigens

11.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. The import permit covers the requirements for the importation of antigens derived from multicellular organisms (plants and animals) or synthetic (non-biological) material only.

The import permit does not cover the requirements for the importation of whole microorganisms (both viable and non-viable) and antigens derived from microorganisms (which include viruses, bacteria and prions), or for the importation of antisera.

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

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

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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.

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

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

12. Cell lines and/or supernatant fluid

12.1. Biosecurity Pathway

a. The goods must be cell lines and/or supernatant fluid derived from humans, guinea pigs, rats, mice, hamsters, rabbits, insects, and hybridomas of these species only. The goods must not be primary cells.

Import conditions prior to arrival in Australian territory

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:

A statement that:

1. the cell line has shown no signs of contamination, including cytopathic effects, with adventitious infectious agents or microbial contamination
2. 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. 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. 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. the cell line is greater than 2 years old.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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.

13. Cell lines from non-laboratory animals

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

13. Cell lines and/or supernatant fluid

13.1. 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.

Import conditions prior to arrival in Australian territory

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:

A statement that:

1. the cell line has shown no signs of contamination, including cytopathic effects, with adventitious infectious agents or microbial contamination
2. 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. 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. 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. 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.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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.

14. Culture media containing no greater than 20ml or 20g animal derived material

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

14.	Culture media (no greater than 20ml or 20g animal derived material)

14.1. Biosecurity Pathway

Culture media supplements may also be imported:

1. when specifically designed for use with culture media
2. where they can meet all import conditions
3. whether or not they are imported in the same consignment (separate to the culture media) or in a separate consignment.

Import conditions prior to arrival in Australian territory

a. These import conditions allow for the import of culture media that contains no greater than 20ml or 20g of animal derived material in each individual unit.

b. The goods must be pre-packaged and ready for use by the end user.

c. The goods must not be totally comprised of blood and/or sera.

d. The goods must not contain fruit.

e. 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:

A statement that the goods:

1. are pre-packaged and ready for use by the end user
2. do not contain greater than 20ml or 20g of animal derived material for each individual unit
3. are not totally comprised of blood and/or sera
4. do not contain fruit.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

OR

The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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

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

h. 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.

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.

15. Genetic material derived from multicellular organisms (Standard Permit)

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

15. Genetic material

15.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the importation of purified genetic material (nucleic acids) derived from multicellular organisms (excluding plants and fungi).

b. These conditions do NOT allow the importation of:

1. Genetic material derived from microorganisms and infectious agents (including prions).
2. Cloning vectors or expression systems.
3. Genetic material derived from plants.
4. Genetic material derived from fungi.

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

d. 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 that:

1. The genetic material is highly purified and unable to replicate; and
2. The genetic material is derived from multicellular organisms (excluding plants, fungi or prions from any species) only.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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. 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.

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. Genetic material derived from or homologous to sequences from disease agents (Standard Permit)

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

16. Genetic material

16.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the import of purified genetic material derived from, or homologous to sequences from, disease agents* excluding:

1. Pathogens of animal biosecurity concern for biological products, as published on the Department of Agriculture, Fisheries and Forestry's website
2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation
3. Poliovirus
4. Monkeypox
5. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

*Disease agent includes but is not limited to microorganism, parasite, virus, prion, plasmid or viroid.

b. The import of cloning and expression vectors and viral vectors is not permitted.

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

d. The genetic material must not be derived from or homologous to sequences from any prion (whether naturally occurring, chemically synthesized or recombinant protein).

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:

Evidence that:

1. The genetic material has been highly purified and is unable to replicate.
2. The genetic material is derived or homologous to sequences from disease agents, excluding pathogens of animal biosecurity concern for biological products (as published on the Department of Agriculture, Fisheries and Forestry's website), a disease agent causing a Listed Human Disease (as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation), Poliovirus, Monkeypox or plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).
3. The goods are not cloning/expression vectors or viral vectors.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.

2. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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

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

h. 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.

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.

17. Standard laboratory vectors for routine scientific purposes

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

17. Genetic material

17.1. Biosecurity Pathway

The intent of this permit is to facilitate the import of nucleic acids and/or cloning and viral expression systems for routine scientific purposes in laboratories. This permit is not to be used as a means to either import entire genomes of exotic microorganisms and infectious agents or segments of exotic microorganisms and infectious agents to be later assembled into infectious agents or microorganisms other than plasmids.

Import conditions prior to arrival in Australian territory

a. The goods must be plasmids, cosmids, yeast artificial chromosomes, bacterial artificial chromosomes, *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors, and/or the following viral vectors only:
   1. Adeno-associated virus (AAV) vectors.
   2. Human immunodeficiency virus (HIV) vectors.
   3. Bacteriophages lambda, lambdoid and Ff.
   4. Polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV).

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

c. The vectors must:
   1. have been deliberately constructed for a specific purpose such as cloning and expression or production of viral vectors
   2. in the case of plasmids or cosmids be non-integrative and non-conjugative
   3. in the case of viral vectors be replication incompetent or unable to produce a viral or infectious particle
   4. not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions
   5. not contain nucleic acid derived from and/or associated with, or homologous to the following:
      5.1. Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
      5.2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.
      5.3. Poliovirus
      5.4. Monkeypox
      5.5. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

d. The vectors must not contain the whole genome or a whole autonomous genomic region* of any organism other than sequences derived from or homologous to sequences from:

1. Multicellular organisms (excluding fungi).
2. Standard laboratory microorganisms and infectious agents.
3. Approved starter cultures, as published on the Department of Agriculture, Fisheries and Forestry's website.
4. Vectors as described above.

> Autonomous genomic regions are distinct nucleic acid sequences which can be replicated independently such as transposons, entire viral genomes, entire segments of a segmented viral genome, and natural plasmids.
>
> A natural plasmid is a plasmid which naturally occurs in a bacterium, protozoan or a multicellular organism that has not been manipulated or genetically engineered.

e. The vectors must not be designed to increase the following traits in the organisms they are transduced, transformed or introduced into (other than antibiotic resistance genes used to facilitate selection of the vector):
   1. Pathogenicity
   2. Virulence
   3. Ability to replicate and invade host cells
   4. Host range and/or susceptibility
   5. Increase mode of transmission to animals
   6. Ability to evade the host immune system
   7. Increased cytotoxic or oncogenic effects

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

g. The product must not be on a whole seed, whole grain or animal derived carrier (other than lactose).

h. The vectors may be imported as purified genetic material, or may be imported in:
   1. Any microorganisms or virus listed in the standard laboratory microorganisms and infectious agents.
   2. Approved starter cultures, as published on the Department of Agriculture, Fisheries and Forestry's website.

i. 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:
   1. The goods are plasmids, cosmids, yeast artificial chromosomes, bacterial artificial chromosomes, *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors, and/or the following viral vectors only:
      1.1. Adeno-associated virus (AAV) vectors.
      1.2. Human immunodeficiency virus (HIV) vectors.
      1.3. Bacteriophages lambda, lambdoid and Ff.
      1.4. Polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus

(AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV).

2. The vectors:
   2.1. Have been deliberately constructed for the purpose of cloning and expression or production of viral vectors.
   2.2. In the case of plasmids or cosmids are non-integrative and non-conjugative.
   2.3. In the case of viral vectors are replication incompetent and unable to produce a viral or infectious particle.
   2.4. Do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions.
   2.5. Do not contain nucleic acid derived from and/or associated with, or homologous to the following:
   - Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
   - Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.
   - Poliovirus.
   - Monkeypox.
   - All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).
3. The vectors do not contain the whole genome or a whole autonomous genomic region* of any organism other than sequences derived from or homologous to sequences from:
   3.1. Multicellular organisms (excluding fungi), and/or
   3.2. Standard laboratory microorganisms and infectious agents
   3.3. Approved starter cultures, as published on the Department of Agriculture, Fisheries and Forestry's website.
4. The vectors are not designed to increase the following traits in the organisms they are transduced, transformed or introduced into (other than antibiotic resistance genes used to facilitate selection of the vector):
   4.1. Pathogenicity.
   4.2. Virulence.
   4.3. Ability to replicate and invade host cells.
   4.4. Host range and/or susceptibility.
   4.5. Increase mode of transmission to animals.
   4.6. Ability to evade the host immune system.
   4.7. Increased cytotoxic or oncogenic effects.
5. The proteins, coding regions, and genetic information included in any vectors are not derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species, and
6. The product is not on a whole seed, whole grain or animal derived carrier (other than lactose).

Import conditions after arrival in Australian territory

j. It is the importer’s responsibility to ensure the import conditions are met and the goods (including derivatives) are only used in accordance with the following end use conditions.

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. The goods may be used for the culturing and isolation of microorganisms and infectious agents, including the following:
   2.1. Propagating microorganisms and infectious agents from the goods, and/or
   2.2. inserting or inoculating microorganisms or infectious agents into eukaryotic or prokaryotic cell cultures.

> Culturing is the multiplication of microorganisms, infectious agents, or cell cultures for scientific purpose.

l. Synthesis of replication-competent microorganisms, infectious agents, or homologues from the goods is restricted to plasmids that are non-conjugative and non-integrative, and not made for the purpose of creating/transcribing or expressing a separate replication competent infectious agent.

> Synthesis of replication-competent microorganisms, infectious agents or homologues refers to the process of modifying or constructing microorganisms and infectious agents which can replicate within eukaryotic or prokaryotic cells.

m. The goods must not deliberately be used in circumstances where recombination and reassortment events with any other virus could reasonably be expected to occur, including coinfection of animals or cell lines with related or homologous infectious agents.

n. The goods must be labelled with the end use conditions on the smallest individually packaged unit.
OR
The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

o. Imported material and derivatives are not to be used with genes derived from and/or associated with, or homologous to the following without further assessment by the Department of Agriculture, Fisheries and Forestry:

1. Pathogens of animal biosecurity concern for biological products, as published on the Department of Agriculture, Fisheries and Forestry's website.
2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.
3. Poliovirus.
4. Monkeypox.
5. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

Additional information

p. **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.

q. 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.

r. 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. Standard laboratory vectors for nucleic acid sequencing

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

18. Genetic material

18.1. Biosecurity Pathway

The intent of this permit is to facilitate the import of nucleic acid within vectors for genetic sequencing in laboratories. Vectors imported under this permit are not to be used for any other purposes.

Import conditions prior to arrival in Australian territory

a. The goods must be plasmids, cosmids, yeast artificial chromosomes, bacterial artificial chromosomes, *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors, and/or the following viral vectors only:
   1. Adeno-associated virus (AAV) vectors.
   2. Human immunodeficiency virus (HIV) vectors.
   3. Bacteriophages lambda, lambdoid and Ff.
   4. Polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV).

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

c. The vectors must not contain nucleic acid derived from and/or associated with, and/or homologous to any of the following:
   1. Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
   2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.
   3. Poliovirus.
   4. Monkeypox.
   5. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

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

e. Viral vectors must be replication incompetent or unable to produce a viral or infectious particle.

f. The product must not be on a whole seed, whole grain or animal derived carrier (other than lactose).

g. The vectors may be imported as purified genetic material, or may be imported in:
   1. Any microorganisms or virus listed in the standard laboratory microorganisms and infectious agents.

2. Approved starter cultures, as published on the Department of Agriculture, Fisheries and Forestry's website.

h. 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:

A statement that the goods:

1. Are plasmids, cosmids, yeast artificial chromosomes, bacterial artificial chromosomes, *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors, and/or the following viral vectors only:

   1.1. Adeno-associated virus (AAV) vectors.

   1.2. Human immunodeficiency virus (HIV) vectors.

   1.3. Bacteriophages lambda, lambdoid and Ff.

   1.4. Polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV).

2. Do not contain nucleic acid derived from and/or associated with, or homologous to the following:

   2.1. Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.

   2.2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.

   2.3. Poliovirus.

   2.4. Monkeypox.

   2.5. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

Import conditions after arrival in Australian territory

i. It is the importer’s responsibility to ensure the import conditions are met and the goods (including derivatives) are only used in accordance with the following end use conditions.

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

1. The goods must be used for nucleic acid sequencing only.
2. The goods must not be exposed to or used in animals, plants, microorganisms, cell cultures or the environment, and must not be used in or on humans.
3. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

k. Synthesis of replication-competent microorganisms, infectious agents, or homologues from the goods is not permitted.

Synthesis of replication-competent microorganisms, infectious agents or homologues refers to the process of modifying or constructing microorganisms and infectious agents which can replicate within eukaryotic or prokaryotic cells.

Additional information

l. **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.

m. 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.

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

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

19.	Microorganisms (including viruses)

Some products may require specialised storage and/or handling.

19.1. Biosecurity Pathway

These conditions are intended for the import of standard laboratory microorganisms and infectious agents. They are not intended to be used for the import of cloning and expression vectors encased in standard laboratory microorganisms and infectious agents or the import of viral vectors.

Import conditions prior to arrival in Australian territory

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 list.

b. The import of cloning and expression vectors (including importation in microorganisms and infectious agents listed in standard laboratory microorganisms (including viruses) and viral vectors is not permitted.

c. The goods must not knowingly contain cloning and expression vectors that have been deliberately constructed for a specific purpose such as cloning and expression or production of viral vectors.

d. 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.

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

f. Each culture, derivative or sequence 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 cultures.
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.

g. The goods must meet biosecurity requirements.

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

A statement that the goods are not:

1. viral vectors
2. being imported containing cloning and expression vectors that have been deliberately constructed for a specific purpose such as cloning and expression or production of viral vectors.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

i. **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.

j. 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.

k. 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.

20. Prepared culture media including pre-poured plates, swabs and vials no greater than 50 mL or 50 g

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

20. Prepared media including pre-poured plates, swabs and vials

20.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the import of prepared microbiological culture media that is pre-packaged and ready for use by the end user including:
   1. plates e.g. petri dishes containing media
   2. swabs e.g. transport swabs
   3. dip slides
   4. vials, and/or
   5. tubes (including slopes).

b. The goods must contain no greater than 50 mL or 50 g of media per individually packaged unit.

c. The goods must be sterilised prior to arrival in Australian territory.

d. The goods must not be or contain foetal bovine serum (FBS).

e. 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:

   A statement that the goods:
   1. are prepared microbiological culture media, pre-packed and ready for use by the end user.
   2. contain no greater than 50 mL or 50 g of media for each individually packaged unit.
   3. have been sterilised.
   4. are not and do not contain foetal bovine serum (FBS).

Import conditions after arrival in Australian territory

f.
   1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in any plants, humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
   2. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.
   3. The goods must be labelled with the end use conditions on the smallest individually packaged unit.
      OR
      The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

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

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.

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

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

h. 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.

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.

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

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

21. Purified laboratory reagents, toxins and venoms

21.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the import of the following categories of 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. recombinant proteins and peptides (excluding antibodies and prions)
   11. lipids (includes fats, waxes, sterols, glycerides, phospholipids and their derivatives)
   12. co-factors
   13. other proteins (e.g. glycoproteins, lipoproteins, peptides and derivatives) not listed under any of the categories 1-10 above, excluding proteins derived from:
   13.1. Pathogens of animal biosecurity concern for biological products, as published on the department's website
   13.2. Disease agents causing Listed Human Diseases, as legislated under the Biosecurity (Listed Human Disease) Determination 2016 and published on the Federal Register of Legislation.

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

c. The goods must not be:
   1. live or infectious material,
   2. genetic material,
   3. prions (derived from an organism, recombinant protein, or synthetic), or
   4. antibodies (derived from an organism, or recombinant protein)

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

e. Composite products (products containing several ingredients) may contain synthetic material (excluding genetic material), and must not contain any microbial, animal or plant derived ingredients other than:
   1. Purified ingredients (as listed in categories 1-13 above)
   2. Approved biological ingredients (Appendix 2) (as per section 39 of Biosecurity (Conditionally Non-prohibited Goods) Determination 2021)

3. Highly refined organic chemicals and substances (as published on the department's website)

> ***Synthetic*** means any good that does not contain any ingredient of biological origin, at any stage of production.

f. 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, including the category of purified ingredients to which the goods belong.
2. Evidence that:

   2.1 the goods are not composite products; or

   2.2 the goods are composite products containing the following ingredients only:
   2.2.1 Purified ingredients (as listed in categories 1-13 above)
   2.2.2 Approved biological ingredients (Appendix 2) (as per section 39 of Biosecurity (Conditionally Non-prohibited Goods) Determination 2021)
   2.2.3 Highly refined organic chemicals and substances (as published on the department's website)
3. A statement that the goods have been purified using a validated method that removes/inactivates infectious material.
4. A statement that the goods are not live or infectious material, genetic material, prions or antibodies.
5. Evidence that the goods are in quantities of no greater than 20ml or 20g for each individually packaged unit.
6. For import of other proteins (including derivatives e.g. peptides) that are not listed under categories 1-12 above (e.g. albumins, enzymes) and that are not 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 derived from Pathogens of animal biosecurity concern for biological products, as published on the department's website or Disease agents causing Listed Human Diseases, as legislated under the Biosecurity (Listed Human Disease) Determination 2016 and published on the Federal Register of Legislation.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in animals other than laboratory animals and must not be used in humans or the environment. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.
2. The goods may be used in plants (including macro-algae) under laboratory conditions,
3. Microorganisms or infectious agents must not be intentionally cultured or isolated from the materials imported under this permit.
4. Any microorganisms or infectious agents (including derivatives) within the imported goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.

5. The goods must be labelled with the end use conditions on the smallest individually packaged unit.
   OR
   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

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.

22. Potable water samples sourced from a conveyance for laboratory studies

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

22. Soil and water samples

22.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. 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:

A statement that the goods:

1. are potable water that have come from a conveyance in Australian territory
2. are individually packaged in units of no greater than 1L or 1kg.

Import conditions after arrival in Australian territory

b. 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.

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

1. The goods must not be exposed to or used in animals, plants, or the environment, and must not be used in or on humans.
2. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

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

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

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

Additional information

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.

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. 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.

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.

23. Sediment and related samples from the sea or ocean floor

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

23. Soil and water samples

23.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. Samples must only be sourced from the *benthic zone of oceans or seas (i.e. sediment from the sea floor/ocean floor) within the **neritic or oceanic zones. Samples must not be sourced from the following:

1. **the intertidal zone (including estuaries)
2. aquaculture sites
3. inland seas.

*The benthic zone, or benthos, is the lowest ecological region in a body of water. The benthic zone begins at the shoreline and extends along the bottom of a body of water. In the case of the seas and oceans, the benthic zone ranges from the intertidal zone to the deepest ocean trenches. It comprises the sediment surface and some sub-surface layers and receives the organic material from the upper layers of the ocean.

**As the benthic zone exists across all regions of the seas and oceans, benthic samples may be obtained from various vertical ocean zones. These are the intertidal zone, the neritic zone and the oceanic zone. The intertidal zone is the zone that is above water at high tide and submerged at low tide. The neritic zone is the shallow part of the ocean extending from the shoreline to the edge of the continental shelf. The neritic zone is always submerged and extends to depths of 200 metres. The oceanic zone is the region of open sea beyond the continental shelf and can be over 10,000 metres deep in the deepest trenches.

b. Samples must undergo one of the following treatments prior to import, or immediately after import:

1. freezing to achieve a consistent temperature throughout of -20°C
2. heating to achieve a consistent temperature throughout of 56°C
3. ionising radiation to achieve a minimum absorbed dose of 50 kGy, or
4. addition of sodium hypochlorite or calcium hypochlorite to achieve a final concentration of 2,500 ppm chlorine, ensuring thorough mixing through the sample.

Treatment must be performed prior to any other use or analysis of the goods.

c. The goods must meet biosecurity conditions.

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

1. A statement that the goods are sediment and related samples which have been sourced from the benthic zone (i.e. sediment from the sea floor/ocean floor) within the neritic or oceanic zones only.
2. A statement that the goods have not been sourced from the intertidal zone (including estuaries), aquaculture sites or inland seas.
3. For goods that have been treated prior to import, a statement that the goods have undergone one of the following treatments:
   3.1. freezing to achieve a consistent temperature throughout of -20°C
   3.2. heating to achieve a consistent temperature throughout of 56°C

3.3. ionising radiation to achieve a minimum absorbed dose of 50 kGy, or
3.4. addition of sodium hypochlorite or calcium hypochlorite to achieve a final concentration of 2,500 ppm chlorine, ensuring thorough mixing through the sample.

d. Samples must not contain visible animal tissues or whole animals (shells and bones are permissible).

e. The goods must be either:

1. imported in volumes of less than 1 kg or 1 L per individually packaged unit, or
2. mining or geological samples imported in volumes of no greater than 60 kg or 60 L per individually packaged unit for physical and/or chemical analysis only.

Import conditions after arrival in Australian territory

f. 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.

g. If an approved treatment is performed after import, it is the permit holder's responsibility to ensure the treatment is applied effectively and relevant records are kept.

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

1. The goods must not be exposed to or used in animals, plants, microorganisms, cell cultures or the environment, and must not be used in or on humans.
2. The goods must not be used for culture or isolation of microorganisms and infectious agents.
3. Microorganisms and infectious agents must not be cultured or isolated from the materials imported under this permit.
4. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
5. Prior to any liquid disposal via the sewerage system, the goods must have been treated using one of the following methods:
   5.1. freezing to achieve a consistent temperature throughout of -20°C
   5.2. heating to achieve a consistent temperature throughout of 56°C
   5.3. ionising radiation to achieve a minimum absorbed dose of 50 kGy, or
   5.4. addition of sodium hypochlorite or calcium hypochlorite to achieve a final concentration of 2,500 ppm chlorine, ensuring thorough mixing through the sample.

   Note: Treatment can occur either pre-import or post-import.

Additional information

i. **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.

j. 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.

k. 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.

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.

24. Environmental samples for laboratory analysis, culture and isolation not permitted

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

24.	Soil and water samples

24.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. The goods must be:

1. Soil samples (including, but not limited to, subsoil, aquatic or marine soil, sediments, silt)
2. Water samples
3. Dust samples
4. Mining slurry samples
5. Inorganic material contaminated with soil and/or water.

> The goods may also be imported as cores, swabs, and/or filters used on the listed sample types where all conditions can be met.

b. The samples must not be sourced from waste collection or waste treatment facilities (human and/or animal), intensive animal production facilities, farm sites, horticultural sites and/or aquaculture facilities.

c. The imported goods must be free from visible seed, human, animal and plant debris and other biosecurity risk material.

d. Liquid or water samples must be imported in a volume less than or equal to 1 L or 1 kg per individually packaged unit.

e. Solid samples must be imported in units less than or equal to 10 L or 10 kg per individually packaged unit.

f. The goods must meet the following import conditions.

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

A statement that the goods:

1. have not been sourced or sampled from waste collection or waste treatment facilities (human and/or animal), intensive animal production facilities, farm sites and/or aquaculture facilities
2. are free from visible seed, human, animal and plant debris and other non-commodity biosecurity risk material.

Import conditions after arrival in Australian territory

g. The goods are for use at approved arrangement sites class 5. The level of containment must be BC level 1 or higher.

h. The goods must only be directed to AA sites with current approval from the Department of Agriculture, Fisheries and Forestry as a class 5 approved arrangement site at the time of

importation and until such time that all imported material and its derivatives are removed for disposal or export.

i. The goods and their derivatives shall not be removed from these sites, except for treatment, disposal or export, without the prior approval of the Director of Biosecurity.

j. The goods may be transferred between approved arrangement site classes 5.1 (or higher). All records of transfer must be maintained for audit purposes.

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

1. The goods must not be exposed to or used in animals, plants, microorganisms, cell cultures or the environment, and must not be used in or on humans.
2. The goods must not be used for culture or isolation of microorganisms and infectious agents, or for the synthesis of replication-competent microorganisms or infectious agents.
3. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under the permit conditions in this permit case.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.
   OR
   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

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.

Records of treatment, disposal and release of all imported items must be retained by the AA site for Department of Agriculture, Fisheries and Forestry audit purposes.

l. The goods may be released from biosecurity containment for further in vitro analysis if the samples are subjected to any of the sample preparation or analysis techniques listed below:

1. One or a combination of the following:
   1.1. Solid phase extraction (SPE), liquid-liquid extraction (LLE) or solid-liquid extraction (SLE) using organic solvents such as hexane, isooctane, carbon tetrachloride, chloroform, tetrahydrofuran, dichloromethane (methylene dichloride), acetone, isopropanol, methanol, ethyl acetate, and acetonitrile (methyl cyanide, cyanomethane).
   1.2. Atomic absorption spectrometry
   1.3. The use of a flame atomiser
   1.4. Induction coupled plasma analysis
   1.5. Gas chromatography
   1.6. Liquid chromatography
   1.7. Mass spectrometry
   1.8. Optical emission spectrometry

1.9. Thermal, electron or chemical ionisation
1.10. Thermoluminescence dating in which the sample material is progressively heated from 110°C to at least 350°C (excludes low temperature thermoluminescence)
1.11. High temperature combustion (>600°C)

2. Sample preparation which includes autoclaving at a minimum of 121°C and 15psi for 30 minutes.
3. Complete acid digestion using one or a combination of the following: concentrated hydrochloric (HCl 32-37%/~12M), nitric (HNO3 65-70%/~16M), perchloric (HClO4 ~70%/11M), sulphuric (H2SO4 95- 98%/~18M) and hydrofluoric (HF 40-48%/~27M) acid in:
3.1. A microwave digestion system at ≥150°C and ≥ 15psi for at least 20 minutes; or
3.2. A heating block at a minimum of 100°C for at least 30 minutes.
4. Acidification at less than or equal to pH 2.0 throughout the final sample for at least 30 minutes.
5. Alkalisation at greater than or equal to pH 10 throughout the final sample for at least 30 minutes.

m. Genetic material extracted from imported samples may be released from biosecurity containment provided all of the following conditions are met:

1. The genetic material must be extracted using a standard laboratory procedure that lyses cells, and degrades lipids, proteins and other molecules, and results in a purified DNA and/or RNA product that is unable to replicate.
2. Individual sample sizes must be 2 mL or 2 g or less and in sealed containers.
3. Genetic material removed from AA site containment must be used for *in vitro* analytical procedures only (e.g. PCR, sequencing, Northern/Southern blotting).
4. Genetic material must not be used for the synthesis of replication-competent microorganisms, infectious agents, or homologues.
5. Genetic material and derivatives must not be directly or indirectly exposed to animals.
6. Any sample remnants, sample containers and disposable equipment that have contacted the samples must be subjected to a Department of Agriculture, Fisheries and Forestry approved treatment method prior to disposal OR the genetic material, its containers and disposable equipment that has contacted the genetic material must be treated as "potentially contaminated wastes" as described in section 12 of AS/NZS 2243.3 Safety in Laboratories Part 3: Microbiological safety and containment.

n. The goods may be treated using one of the following treatment methods. After treatment, the goods may then be released from biosecurity control.

Soil samples (and other non-liquid goods)

1. dry heat treatment at 160°C for 2 hours (sample must not exceed 500g in weight) (applied in the current AA or AA class 12.3 or 4.1), or
2. heat treatment in an autoclave at 121°C, 103kPa (15 psi) for 30 minutes (applied in the current AA or AA class 8.3), or
3. heat treatment in an autoclave at 134°C, 103kPa (15 psi) for 4 minutes (applied in the current AA or AA class 8.3), or
4. ionising radiation to a level that achieves a minimum absorbed dose of 50kGy (applied in AA class 4.2).

Water samples (and other liquid goods)

1. heat treatment in an autoclave at 121°C, 103kPa (15 psi) for 30 minutes (applied in current AA or AA class 8.3), or
2. heat treatment in an autoclave at 134°C, 103kPa (15 psi) for 4 minutes (applied in current AA or AA class 8.3), or
3. heat treatment at a minimum core temperature of 100°C for at least 30 minutes (applied in the current AA or AA class 12.3 or 4.1), or
4. ionising radiation to a level that achieves a minimum absorbed dose of 50kGy (applied in AA class 4.2).
5. addition of sodium hypochlorite to water to a final chlorine concentration of 2,500 ppm, stirring the contents and allowing a standing time of 2 hours before disposal into the sewerage system.
6. addition of calcium hypochlorite to water to a final chlorine concentration of 2,500 ppm, stirring the contents and allowing a standing time of 2 hours before disposal into the sewerage system.

o. On completion of work all imported materials and the direct or indirect derivatives thereof must be disposed of by treatment methods (as listed) or other methods approved in writing by the Director of Biosecurity.

Additional information

p. **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.

q. 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.

r. 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.

25. Nucleic Acid Amplification (NAA) test kits

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

25. Test kits

25.1. 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.

Import conditions prior to arrival in Australian territory

a. The goods must be commercially manufactured and packaged.

b. The goods must be Nucleic Acid Amplification (NAA) test kits only (or individual components specifically designed for use with kits eligible for import under these conditions).

c. The goods contain nucleic acid up to 1000 nucleotides, enzymes and chemical buffers only.

d. The goods must meet biosecurity requirements.

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

A statement that the goods:

1. are Nucleic Acid Amplification (NAA) test kits only (or individual components specifically designed for use with kits eligible for import under these conditions)
2. 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.

The manufacturer’s declaration must be supplied by either a legal manufacturer, or the individual manufacturing site.

Note: The manufacturing declaration does not need to be issued from within the country of manufacture.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in plants, or the environment, and must not be used in or on humans.
2. The goods must not be exposed to or used in animals. Only unused swabs or spatulas may be exposed to or used in animals.
3. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.
4. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
5. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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.

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, Fisheries and Forestry 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.

26. Test kits not testing for disease agents

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

26. Test kits

26.1. 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.

Import conditions prior to arrival in Australian territory

a. The goods must only be test kits, which:

1. do not test for disease agents.
2. do not contain disease agents (live, live attenuated or inactivated) or their derivatives (e.g. antigens).
3. do not contain any components raised against disease agents (e.g. antibodies).

Disease agent includes but is not limited to:

- Microorganism
- Parasite
- Virus
- Prion
- Plasmid
- Viroid

b. All animal derived material must be 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.

c. The goods must be commercially manufactured and packaged.

d. The goods must meet biosecurity requirements.

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

A statement that:

1. 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. 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.

The manufacturer’s declaration must be supplied by either a legal manufacturer, or the individual manufacturing site.

Note: The manufacturing declaration does not need to be issued from within the country of manufacture.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in plants, cell cultures or the environment, and must not be used in or on humans (except for allergy tests to be applied to the skin).
2. The goods must not be exposed to or used in animals. Only unused swabs or spatulas may be exposed to or used in animals.
3. The goods must not be used for culture or isolation of microorganisms and infectious agents.
4. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.
5. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
6. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

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.

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.

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, Fisheries and Forestry 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.

27. Test kits for disease agents excl. Listed Human Diseases and Pathogens of Animal Biosecurity Concern

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

27.	Test kits

27.1. Biosecurity Pathway

These conditions allow for the import of test kits testing for:

1. Disease agents, excluding Pathogens of Animal Biosecurity Concern 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.

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.

Import conditions prior to arrival in Australian territory

a. The goods must be test kits (or individual components specifically designed for use with kits eligible for import under these conditions) only.

b. The goods must be commercially manufactured and packaged.

c. All components of the goods derived from (or raised against) disease agents and cell lines (e.g. antigen, antibody, positive control, calibrator) must have been inactivated and/or be incapable of replicating.

d. The goods do not test for, or contain the following (including live, live attenuated or inactivated) microorganisms or infectious agents, or components derived from or raised against these agents (i.e. antibodies):

1. Listed Human Diseases,
2. Pathogens of Animal Biosecurity Concern,
3. Mpox, or
4. Poliovirus.

e. All animal derived material contained in these test kit(s) must be 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.

f. The goods must meet biosecurity requirements.

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

A statement that:

1. The goods are test kits (or individual components specifically designed for use with kits eligible for import under these conditions) only.
2. All components of the goods derived from (or raised against) disease agents and cell lines (e.g. antigen, antibody, positive control, calibrator) have been inactivated and/or are incapable of replicating.
3. The goods do not test for, or contain the following (including live, live attenuated or inactivated) microorganisms or infectious agents, or components derived from or raised against these agents (i.e. antibodies):
   3.1. Listed Human Diseases
   3.2. Pathogens of Animal Biosecurity Concern
   3.3. Mpox, or
   3.4. Poliovirus.
4. 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 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.

The manufacturer’s declaration must be supplied by either a legal manufacturer, or the individual manufacturing site.

Note: The manufacturing declaration does not need to be issued from within the country of manufacture.

Import conditions after arrival in Australian territory

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

1. The goods must not be exposed to or used in plants, or the environment, and must not be used in or on humans.
2. The goods must not be exposed to or used in animals. Only unused swabs or spatulas may be exposed to or used in animals.
3. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.
4. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
5. The goods must be labelled with the end use conditions on the smallest individually packaged unit.
   OR
   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Notice to end users

1. Certain disease agents are considered to be nationally notifiable. In some jurisdictions the use of materials containing and/or testing for notifiable

disease/s is restricted unless approval is granted by the Chief Veterinary Officer or relevant state or territory authority.

2. The permit holder must be aware of the relevant state or territory regulation prior to importing, distributing and using the goods.
3. It is the responsibility of the permit holder to inform end users of the imported test kits of their obligations.

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. 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.

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.

Appendix 1: List: Family Salmonidae

Salmonid species approved for export to Australia

All species in the following genera:

Brachymystax spp.
Coregonus spp.
Hucho spp.
Oncorhynchus spp.
Parahucho spp.
Prosopium spp.
Salmo spp.
Salvelinus spp.
Salvethymus spp.
Stenodus spp.
Thymallus spp.
Plecoglossus spp.

Appendix 2: List: Section 39 of Biosecurity (Conditionally Non-prohibited Goods) Determination 2021

Biological material	
Item	**Biological material**
1	Alcohols
2	Carminic acid
3	Citric acid
4	Colloidal oatmeal
5	Cultures of *Saccharomyces cerevisiae* (or a derivative of a pure culture of *Saccharomyces cerevisiae*)
6	Cyclosporin (except if manufactured using materials of terrestrial animal or avian origin)
7	Diethylaminoethyl (DEAE) dextran (except if manufactured using materials of terrestrial animal or avian origin)
8	Essential oils
9	Esters
10	Fish oil (other than salmon oil)
11	Glucosamine, chondroitin or chitosan of aquatic animal origin (except if derived from fish of the family Salmonidae or intended for veterinary therapeutic use in aquatic animals)
12	Green lipped mussel powder from New Zealand (except if intended for veterinary therapeutic use in aquatic animals)
13	Highly processed biochemicals derived from wool grease (including cholesterol, cholecalciferol vitamin D3, lanolin and lanolin alcohols)
14	Homeopathic preparations
15	Lactic acid
16	Lactose (except in products intended for administration to food producing animals in their feed or water ration)
17	Natural flavourings (except if manufactured using materials of terrestrial animal or avian origin)

18	Neatsfoot oil, if present in products for topical application to humans or animals that are companion or performance animals (such as dogs, cats or horses)
19	Pectins
20	Plant acids
21	Plant extracts (other than flours or powders)
22	Plant gums
23	Plant juices
24	Plant oils
25	Plant waxes
26	Purified amino acids (other than those derived from neural material)
27	Purified antibiotics or antimycotics manufactured without using materials of terrestrial animal or avian origin (except if intended for veterinary therapeutic use in aquatic animals)
28	Purified avermectin compounds manufactured without using materials of terrestrial animal or avian origin (except if intended for veterinary therapeutic use in aquatic animals)
29	Purified corticosteroid manufactured without using materials of terrestrial animal or avian origin
30	Purified hyaluronic acid manufactured without using materials of terrestrial animal or avian origin (except if intended for veterinary therapeutic use in aquatic animals)
31	Purified milbemycin compounds manufactured without using materials of terrestrial animal or avian origin (except if intended for veterinary therapeutic use in aquatic animals)
32	Purified spinosyn compounds, if present in products for use in humans or animals that are companion or performance animals (such as dogs, cats or horses)
33	Resins
34	Starches
35	Sugars (other than lactose)

36	Tallow derivatives that are methyl oleate, oleic acid, glycerol or stearates, produced by hydrolysis, saponification or transesterification using high temperature (above 200°C) and pressure
37	Tinctures (except if manufactured using materials of terrestrial animal or avian origin)
38	Vinegars
39	Vitamins or provitamins
40	Water
41	Xanthan gum

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