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: 0011019934

Valid for: multiple consignments between 28 August 2025 and 28 August 2030

This permit is issued to: PROTEOMICS INTERNATIONAL PTY LTD
6 Verdun Street
QQ Block
QEII Medical Centre
NEDLANDS WA 6009
AUSTRALIA

Attention: Miss Hitormi Lim

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. 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 6
2. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excluding reproductive material) sourced from avians only	Page 9
3. Antibodies		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	

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: 11 August 2025

Permit Conditions:	Purified antibodies raised against inorganic or multicellular antigens (Standard Permit)	Page 12

4. 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 14

5. Human fluids and tissues		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Human fluids and tissues that are free from listed diseases	Page 16

6. 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 18

7. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Test kits testing for Listed Human Diseases and not included on the ARTG (Standard)	
Permit Conditions:	Test kits testing for Listed Human Diseases	Page 21

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) sourced from bovines only	Page 24

9. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excluding reproductive material) sourced from camelids only	Page 27

10. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excl. viable reproductive material) sourced from captive primates only	Page 30

11. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	

Permit Conditions:	Animal fluids and tissues (excluding reproductive material) sourced from cervines (deer) only	Page 33

12. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excl. reproductive material) sourced from equines, containment required	Page 36

13. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excl. reproductive material) sourced from equines only	Page 39

14. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excluding reproductive material) sourced from ovines and caprines only	Page 42

15. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excluding reproductive material) sourced from suids (porcines) only	Page 45

16. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Salmonidae (salmon) fish fluids and tissues (excluding reproductive material)	Page 48

17. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excluding reproductive material) from species, other than those excluded	Page 51

18. Cell lines and/or supernatant fluid		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Cell lines from non-laboratory animals	Page 54

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

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

Important information about this permit and the import of goods

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

Information about this permit

Authority to import

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

Compliance with permit conditions and assessment and management of biosecurity risk

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

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

Change of import conditions

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

General information about importing goods

Notification of import

Notification of the import must be provided to the Department of Agriculture, Fisheries and Forestry for all imported goods other than goods imported as accompanied baggage or goods imported via the mail and not prescribed under *the Customs Act 1901,* or where other exceptions specified in the *Biosecurity Regulation 2016* apply. Notification must be provided in accordance with section 120 of the *Biosecurity Act 2015* and Part 1 of Chapter 2 of the *Biosecurity Regulation 2016*. Please refer to 'Sending your goods to Australia' on the Department of Agriculture, Fisheries and Forestry website.

Provision of required documentation

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

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

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

Non-commodity cargo clearance

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

Fees

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

Compliance with other regulatory provisions

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

Permit conditions

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

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

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

1.	Antibodies

1.1. 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.

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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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. Cell lines of laboratory animal, insect and human origin

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

4.	Cell lines and/or supernatant fluid

4.1. 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.

5. Human fluids and tissues that are free from listed diseases

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

5.	Human fluids and tissues

5.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

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

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

1. A Listed Human Disease. Listed Human Diseases are those that are listed under the *Biosecurity (Listed Human Diseases) Determination 2016*, which is published on the Federal Register of Legislation; and/or
2. Mpox, and/or
3. Polio.

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

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

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

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:

i. **Sourcing**

A statement that the specimens:

1. were only taken from persons not suspected to be infected with and not diagnosed with a Listed Human Disease, mpox or polio
2. are not known to be infected with any Listed Human Diseases, pathogen of animal biosecurity concern, mpox or poliovirus.

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).

Related Information:

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

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.

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

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

6.	Purified laboratory reagents, toxins and venoms

6.1. 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 1) (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 1) (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.

7. Test kits testing for Listed Human Diseases

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

7.	Test kits

7.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the importation of the following goods:

1. test kits testing for 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, and
2. associated reagents, standards, controls and calibrators (imported separately from the test kit in the same or separate consignment) that are specifically designed for use with test kits testing for Listed Human Diseases.

b. The goods must be commercially manufactured and packaged for testing Listed Human Diseases for use with human samples only.

c. The goods must be fully finished and require no further re-packaging following import.

d. 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.

e. Any human derived material (e.g. serum or plasma) contained within the goods must not contain (or must not be suspected to contain) infectious disease agents or contain only disease agents that were rendered non-infectious.

f. All animal derived materials contained in the goods must be in volumes of no greater than 20ml or 20g per individually packaged unit. The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived materials contained must not be 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 Manufacturer's declaration:

i. A statement that the goods are test kits (or individual components specifically designed for use with kits eligible for import under these conditions) testing for Listed Human Diseases (as published on the Federal Register of Legislation) for use with human samples only.

AND

ii. A statement that 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.

Where inactivation of disease agents has occurred – the following statements must also be included on the manufacturer's declaration:

- The disease agents that have been inactivated are <*manufacturer to insert name/s of disease agents (genus and species) here*>.
- The inactivation has been achieved using a validated method and then verified by testing to ensure complete inactivation of the disease agent.

AND

iii. A statement of either:

The goods do not contain any human derived materials (e.g. serum and plasma).

OR

All human derived materials (e.g. serum and plasma) included in the goods do not contain (or is not suspected to contain) infectious disease agents.

OR

All human derived materials (e.g. serum and plasma) included in the goods contain only disease agents that have been rendered non-infectious.

Note: Human derived material may be imported in any volume.

AND

iv. A statement that the goods are fully finished and require no further re-packaging.

AND

v. A statement that all animal derived materials contained in the goods are 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 materials 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

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

1. The goods must only be used for human therapeutic or research purposes.
2. The goods must not be exposed to or used in animals, plants, cell cultures or the environment.
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.

Additional information

i. **Department of Health and Aged Care post entry conditions**

All diagnostic samples and human derived materials contained within the goods must be handled using standard precautions as outlined in the Australian Guidelines for the Prevention and Control of Infection in Healthcare, as published on the National Health and Medical Research Council website.

j. **Department of Health and Aged Care – Advice to importers and end users**

A risk assessment must be undertaken to ensure that any specific hazards depending on the particular end use are identified and managed.

k. **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.

l. 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.

m. 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) sourced from bovines only

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. **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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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.

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

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

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

9.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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.

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

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

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

10.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. **Source species**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

2.1. are not reproductive material, or

2.2. the reproductive material is:
2.2.1. non-viable,
2.2.2. is transported at room temperature, and

2.2.3. is not intended for use in artificial insemination (AI) or assisted reproductive treatment (ART).

[The declaration must indicate the option that applies.]

AND

ii. **Animal Health**

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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
[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.

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

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

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

11.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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.

12. Animal fluids and tissues (excl. reproductive material) sourced from equines, containment required

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

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

12.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. **Source species and countries**

The goods must be fluids and tissues sourced from equines only, which resided in countries approved for equine fluids and tissues with containment (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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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. The goods are for use at an approved arrangement site class 5. The level of containment must be BC level 1 or higher.

These approved arrangement site/s must have current approval from the Department of Agriculture, Fisheries and Forestry as a class 5 approved arrangement site/s at the time of importation and until such time that all imported material and its derivatives are removed for disposal or export.

e. If the above conditions cannot be met, or the goods cannot be directed to an appropriate approved arrangement site, the goods must be treated with ionising irradiation to a level that achieves a minimum absorbed dose of 50kGy before being released to the importer. Irradiation on arrival is mandatory, even if the goods have been treated prior to import.

f. **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 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.

g. In addition to the standards for waste disposal outlined in the 5.1 AA standards and ASNZ 2243.3, liquid biosecurity waste which is or has come into contact with imported material in this category must be decontaminated prior to disposal as biosecurity waste by one of the following disinfectant methods:

1. Virkon – final concentration of 10 g per 1 L for at least 10 minutes or as per the manufacturer's instructions.
2. Chlorine (i.e. sodium hypochlorite solutions) – final concentration of 1% (10,000ppm available chlorine) for a minimum of 10 minutes.

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.

13. Animal fluids and tissues (excl. reproductive material) sourced from equines only

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

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

13.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. **Source species and countries**

The goods must be fluids and tissues sourced from equines only, which resided in countries approved for equine 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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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.

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

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

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

14.1. Biosecurity Pathway

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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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.

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

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

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

15.1. Biosecurity Pathway

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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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.

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

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

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

16.1. 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 2) 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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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.

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

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

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

17.1. 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, antigens derived from multicellular organisms, approved starter cultures, or standard laboratory microorganisms (including viruses) list.
   [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.

18. Cell lines from non-laboratory animals

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

18. Cell lines and/or supernatant fluid

18.1. 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.

Appendix 1: 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

Appendix 2: 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.

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