Australian Government
Department of Agriculture, Water and the Environment

Permit to import conditionally non-prohibited goods

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

Permit: 0005624082

Valid for: multiple consignments between 27 August 2021 and 27 August 2023

This permit is issued to: Proteomics International
6 Verdun Street
QQ Block, QEII Medical Centre
NEDLANDS WA 6009
Australia

Attention: Dr Kerryn Garrett

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. 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 5
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 bovines only	Page 8
3. 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 11

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

Tim Carswell
Delegate of the Director of Biosecurity

Date: 27 August 2021

4. 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 14
5. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excluding reproductive material) sourced from cervines (deer) only	Page 17
6. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excl. reproductive material) sourced from equines only	Page 20
7. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excl. reproductive material) sourced from equines, containment required	Page 23
8. Animal fluids and tissues (excl. viable reproductive material)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Animal fluids and tissues (excluding reproductive material) sourced from ovines and caprines only	Page 26
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 suids (porcines) only	Page 29
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:	Salmonidae (salmon) fish fluids and tissues (excluding reproductive material)	Page 32
11. Antibodies		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	

Permit Conditions:	Antibodies purified and raised against synthetic material or antigens from multicellular organisms	Page 35

12. Cell lines and/or supernatant fluid		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Cell lines of laboratory animal, insect and human origin	Page 37

13. 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 39

14. 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 41

15. 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, not included on the ARTG	
Permit Conditions:	Test kits testing for Listed Human Diseases	Page 44

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

Authority to import

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

Compliance with permit conditions and freedom from contamination

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

Compliance with other regulatory provisions

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

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

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

Change of import conditions

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

Notification of import

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

Valid import permit

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

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

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

OR

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

Provision of required documentation

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

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

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

Permit conditions

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

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

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

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

1.1. Biosecurity Pathway

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

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

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

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

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

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

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

2.1. Biosecurity Pathway

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

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

h. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be

subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

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

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

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

3.1. Biosecurity Pathway

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

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

h. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be

subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

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

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

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

4.1. Biosecurity Pathway

a. **Source species**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

2.1. are not reproductive material, or

2.2. the reproductive material is:
2.2.1. non-viable,

2.2.2. is transported at room temperature, and

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

[The declaration must indicate the option that applies.]

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

3.1. the goods are not antisera, or

3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

[The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

g. Under the Biosecurity Charges Imposition (General) Regulation 2016 and Chapter 9, Part 2 of the Biosecurity Regulation 2016, fees are payable to the Department of Agriculture,

Water and the Environment for all services. Detail on how the department applies fees and levies may be found in the Charging guidelines.

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

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

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

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

5.1. Biosecurity Pathway

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

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

h. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be

subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

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

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

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

6.1. Biosecurity Pathway

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**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

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

h. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be

subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

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

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

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

7.1. Biosecurity Pathway

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**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

c. 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, Water and the Environment 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.

d. 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.

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:

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].

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

Approved end use:

1. *in vitro* laboratory studies.

The following end uses are not permitted:

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

It is the importer's responsibility to ensure that the goods are labelled "*in vitro* only" on the smallest packaged unit, prior to distribution. The products may be labelled post entry.

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

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

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

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

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

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.

h. **Commercial administrative conditions**
Documents must be provided with each consignment which:

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

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

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

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

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

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

h. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be

subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

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

a. **Source species and countries**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

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

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

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

h. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be

subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

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

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

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

10.1. Biosecurity Pathway

a. **Source species**

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

b. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are of Salmonidae (salmon) origin only.
2. A statement that the goods are not reproductive material.

AND

ii. **Animal Health**

1. A statement that the goods were sourced from animals with no clinical signs of infectious disease at the time of collection.
2. A statement that the goods have not been deliberately infected with a disease agent.
3. A statement that either:

   3.1. the goods are not antisera, or

   3.2. the antisera has been raised against synthetic material or against antigens derived from multicellular organisms.

   [The declaration must indicate the option that applies].

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

d. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

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

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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

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

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

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

   e.g. 1: Product XRab = Purified protein derived from rabbits

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

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

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

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

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

11. Antibodies

11.1. Biosecurity Pathway

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

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

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

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

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

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

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

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

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

Approved end uses:

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

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

1. in plants
2. in non-laboratory organisms e.g. chickens, sheep, cattle
3. as veterinary vaccines and therapeutics
4. in culturing or isolating microorganisms and infectious agents
5. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

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

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

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

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

g. **Commercial administrative conditions**
Documents must be provided with each consignment which:

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

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

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

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

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

12. Cell lines and/or supernatant fluid

12.1. Biosecurity Pathway

a. The following conditions apply to cell lines and/or supernatant fluid from humans, guinea pigs, rats, mice, hamsters, rabbits, insects, and hybridomas of these species. These conditions do not allow for the importation of primary cells.

b. The cell line must be free of contamination and infectious disease, and must not be inoculated with live or whole inactivated microorganisms, viruses or prions, or any of their derivatives (other than viral DNA which has been used to immortalise the cell line).

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

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

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

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

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

Approved end uses:

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

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

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

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

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

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

1. International (e.g. International Air Transport Association) and domestic

requirements concerning the safe handling, transport and labelling of biological material

2. AS/NZS 2243 Safety in Laboratories standards
3. Office of the Gene Technology Regulator (OGTR) requirements
4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

d. **Commercial administrative conditions**
Documents must be provided with each consignment which:

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

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

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

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

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

13. Human fluids and tissues

13.1. Biosecurity Pathway

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

b. The goods must have been taken from persons with no clinical signs or symptoms of Listed Human Diseases at the time of collection. Listed Human Diseases are those that are listed under the *Biosecurity (Listed Human Diseases) Determination 2016*, which is published on the Federal Register of Legislation (the Listed Human Diseases are also published on the Department of Health's website).

c. The goods must not have been deliberately infected with Listed Human Diseases.

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

1. A statement that the specimens were only taken from persons with no clinical signs or symptoms of a Listed Human Disease.
2. A statement that the specimens have not been infected with a Listed Human Disease.

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**
Approved end uses:

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

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

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

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

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

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

1. International (e.g. International Air Transport Association) and domestic requirements concerning the safe handling, transport and labelling of biological material.
2. AS/NZS 2243 Safety in Laboratories standards.

3. Office of the Gene Technology Regulator (OGTR) requirements.
4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

f. **Commercial administrative conditions**
Documents must be provided with each consignment which:

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

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

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

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

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

14. Purified laboratory reagents, toxins and venoms

14.1. Biosecurity Pathway

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

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

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

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

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

e. The goods must meet biosecurity requirements.

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

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

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

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

Approved end uses:

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

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

1. in plants
2. in non-laboratory organisms e.g. chickens, sheep, cattle
3. as veterinary vaccines and therapeutics
4. in culturing or isolating microorganisms and infectious agents
5. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

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

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

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

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

g. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).

e.g. 1: Product XRab = Purified protein derived from rabbits

e.g. 2: Product AX = Synthetic antibiotic

e.g. 3: Comte = Cheese.

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

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

15. Test kits testing for Listed Human Diseases

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

15. Test kits

15.1. Biosecurity Pathway

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 (the Listed Human Diseases are also published on the Department of Health's website), 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 are 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 contained only disease agents that were rendered non-infectious.

f. All animal derived materials contained in the goods are 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 Department of Health's website) 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.

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

The goods are for *in vitro* use only.

The following end uses are not permitted:

1. The isolation of disease agents from the imported material.
2. The synthesis of replication-competent disease agents or homologues from the imported material.
3. Direct or indirect exposure to animals (including laboratory animals) or plants.
4. Veterinary purposes.

i. **Department of Health 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 – 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.

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.

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.

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, Water and the Environment 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.

Appendix 1: List: Family Salmonidae

Salmonid species approved for export to Australia

All species in the following genera:

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

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