

Permit to import conditionally non-prohibited goods

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

Permit: 0007494775

Valid for: multiple consignments

between 13 June 2023 and 13 June 2025

This permit is issued to: Macquarie University

Macquarie University

Faculty of Science & Engineering

MACQUARIE UNIVERSITY NSW 2109

AUSTRALIA

Attention: Marita Holley

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

Exporter details: Various exporters

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

1. Human fluids and tissues

End use: In vitro use or in vivo use in laboratory organisms

Country of export: Various countries
Country of origin: Various countries

Permit Conditions: Human fluids and tissues that are not known to be infected Page 7

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

End use: In vitro use or in vivo use in laboratory organisms

Country of export: Various countries Various countries

Permit Conditions: Animal fluids and tissues (excluding reproductive material)

sourced from camelids only Page 9

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 bovines only Page 12

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

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

Rebecca Stabler

Delegate of the Director of Biosecurity Date: 29 March 2023

Permit: 0007494775 Page 2 of 81

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 15

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 Various countries

Permit Conditions: Animal fluids and tissues (excl. viable reproductive material)

sourced from captive primates only

Page 18

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 Various countries

Permit Conditions: Animal fluids and tissues (excluding reproductive material)

sourced from cervines (deer) only

Page 21

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 Various countries

Permit Conditions: Animal fluids and tissues (excluding reproductive material)

sourced from ovines and caprines only

Page 24

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 suids (porcines) only

Page 27

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: Salmonidae (salmon) fish fluids and tissues (excluding

reproductive material)

Page 30

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 (excluding reproductive material)

from species, other than those excluded

Page 32

11. Antibodies

End use: In vitro use or in vivo use in laboratory organisms

Country of export: Various countries Various countries

Permit Conditions: Purified antibodies raised against inorganic or multicellular

antigens (Standard Permit)

Page 34

Permit: 0007494775 Page 3 of 81

12. Antibodies End use: In vitro use or in vivo use in laboratory organisms Country of export: Various countries Country of origin: Various countries Permit Conditions: Purified antibodies raised against disease agents, including microorganisms (Standard Permit) Page 36 13. 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 38 14. Antigens End use: In vitro use or in vivo use in laboratory organisms Country of export: Various countries Country of origin: Various countries Permit Conditions: Antigens that are purified and derived from multicellular organisms or synthetic material Page 41 15. 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 43 16. Cell lines and/or supernatant fluid In vitro use or in vivo use in laboratory organisms End use: Country of export: Various countries Country of origin: Various countries **Permit Conditions:** Page 45 Cell lines from non-laboratory animals 17. Culture media (no greater than 20ml or 20g animal derived material) In vitro use or in vivo use in laboratory organisms End use: Country of export: Various countries Country of origin: Various countries Permit Conditions: Culture media containing no greater than 20ml or 20g animal derived material Page 48 18. Genetic material End use: In vitro use or in vivo use in laboratory organisms Country of export: Various countries Country of origin: Various countries Permit Conditions: Genetic material derived from multicellular organisms (Standard Permit) Page 50 19. Genetic material End use: In vitro use or in vivo use in laboratory organisms Country of export: Various countries Country of origin: Various countries Permit Conditions: Genetic material derived from or homologous to sequences

from disease agents (Standard Permit)

Page 52

Date: 29 March 2023

20. Genetic material

Permit: 0007494775 Page 4 of 81

End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Standard laboratory vectors for routine scientific purposes	Page 54
	Standard laboratory vectors for routine scientific purposes	1 age 34
21. Genetic material	T	
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	D 50
Permit Conditions:	Standard laboratory vectors for nucleic acid sequencing	Page 59
22. Microorganisms (included)		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Standard laboratory microorganisms and infectious agents (and derivatives)	Page 62
23 Prepared media includir	ng pre-poured plates, swabs and vials	
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Prepared culture media including pre-poured plates, swabs	
Termit conditions.	and vials no greater than 50 mL or 50 g	Page 64
24 D : 6 11 1		1 450 0 1
24. Purified laboratory reag End use:		
	In vitro use or in vivo use in laboratory organisms Various countries	
Country of export:	Various countries	
Country of origin: Permit Conditions:		
Fernit Conditions.	Purified laboratory material, laboratory reagents, toxins and venoms	Page 66
	Venoms	1 age 00
25. Soil and water samples		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Potable water samples sourced from a conveyance for	D (0
	laboratory studies	Page 69
26. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Nucleic acid amplification (e.g. PCR) test kits (Standard)	
Permit Conditions:	Nucleic Acid Amplification (NAA) test kits	Page 71
27. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Test kits not testing for disease agents (Standard)	
Permit Conditions:	Test kits not testing for disease agents	Page 73
	<u> </u>	

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	

Page 5 of 81

Date: 29 March 2023

Permit: 0007494775

Permit: 0007494775 Page 6 of 81

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 <u>Charging guidelines</u>.

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: 0007494775 Page 7 of 81

Permit conditions

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

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

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

1. Human fluids and tissues

1.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- a. These conditions allow for the import of human fluids and tissues only.
- b. The goods must be sourced from humans with no clinical signs of infectious disease at the time of collection.
- c. The goods must not have been deliberately infected with a disease agent.
- d. There is no requirement for a manufacturer or importer declaration to accompany samples imported into Australian territory.

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

Date: 29 March 2023

3. describe the goods being imported (where not clear). e.g. 1: Product XRab = Purified protein derived from rabbits Permit: 0007494775 Page 8 of 81

- e.g. 2: Product AX = Synthetic antibiotic
- e.g. 3: Comte = Cheese.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 9 of 81

2. Animal fluids and tissues (excluding reproductive material) sourced from camelids 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 camelids only, which resided in <u>countries</u> <u>approved for camelid fluids and tissues</u> (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 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

Permit: 0007494775 Page 10 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 11 of 81

Permit: 0007494775 Page 12 of 81

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

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 <u>countries</u> <u>approved for bovine fluids and tissues</u> (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].

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.

Permit: 0007494775 Page 13 of 81

[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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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.

Permit: 0007494775 Page 14 of 81

Permit: 0007494775 Page 15 of 81

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

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

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

4.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. Source species and countries

The goods must be fluids and tissues sourced from avians only, which resided in <u>countries</u> <u>approved for avian fluids and tissues</u> (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 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

Permit: 0007494775 Page 16 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 17 of 81

Permit: 0007494775 Page 18 of 81

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

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

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

5.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. Source species

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.

Date: 29 March 2023

[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:

Permit: 0007494775 Page 19 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.

Permit: 0007494775 Page 20 of 81

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.

Permit: 0007494775 Page 21 of 81

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

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

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

6.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. Source species and countries

The goods must be fluids and tissues sourced from cervines only, which resided in <u>countries</u> <u>approved for cervine fluids and tissues</u> (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 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

Permit: 0007494775 Page 22 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 23 of 81

Permit: 0007494775 Page 24 of 81

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

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

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

7.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. Source species and countries

The goods must be fluids and tissues sourced from ovines and/or caprines only, which resided in <u>countries approved for ovine and caprine fluids and tissues</u> (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 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

Permit: 0007494775 Page 25 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 26 of 81

Permit: 0007494775 Page 27 of 81

8. Animal fluids and tissues (excluding reproductive material) sourced from suids (porcines) 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 suids (porcines) only, which resided in <u>countries approved for suid fluids and tissues</u> (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 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

Permit: 0007494775 Page 28 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 29 of 81

Permit: 0007494775 Page 30 of 81

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

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

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. 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.

Date: 29 March 2023

e. Post entry/end use conditions

Permit: 0007494775 Page 31 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 32 of 81

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

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. **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.

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. starter cultures (Appendix 2), or
- 4. standard laboratory microorganisms (including viruses) list (Appendix 3).

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.

Import conditions after arrival in Australian territory

e. 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.

f. Post entry/end use conditions

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

Permit: 0007494775 Page 33 of 81

4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

OR

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

Additional information

g. Commercial administrative conditions

Documents must be provided with each consignment which:

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



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

- 1. International (e.g. <u>International Air Transport Association</u>) and domestic requirements concerning the safe handling, transport and labelling of biological material
- 2. AS/NZS 2243 Safety in Laboratories standards
- 3. Office of the Gene Technology Regulator (OGTR) requirements
- 4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.
- h. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 34 of 81

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

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

11. Antibodies

11.1. 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

Permit: 0007494775 Page 35 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 36 of 81

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

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

12. Antibodies

12.1. Biosecurity Pathway

- a. This import permit covers the requirements for the importation of purified antibodies that are raised against disease agents (or antigens that are parts of or produced by disease agents), excluding:
 - 1. <u>Pathogens of animal biosecurity concern for biological products</u>, as published on the Department of Agriculture, Fisheries and Forestry's website; and
 - 2. Disease agents causing <u>Listed Human Diseases</u>, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.
 - *Disease agent includes but is not limited to microorganism, parasite, virus, prion, plasmid or viroid.

Import conditions prior to arrival in Australian territory

- b. The antibodies must not be suspended in whole blood, sera, plasma or ascitic fluid.
- c. The antibodies must not be raised against any prion (whether naturally occurring, chemically synthesized or recombinant protein) from any species.
- d. The antibodies must be purified using either affinity purification or chromatographic purification methods.
- e. The antibodies may be conjugated to chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.
- f. The goods are individually packaged in units of no greater than 20mL or 20g.
- g. The goods must meet biosecurity requirements.
 - To demonstrate compliance with this requirement you must present the following on a Product label, Invoice, Manufacturer's declaration, Exporter's declaration or Supplier's declaration:
 - 1. The name of each antibody; and
 - 2. The name of the antigen each antibody is raised against (including the common and/or scientific name of the disease agent); and
 - 3. A statement that the antibody/ies were not raised against any prions (naturally-occurring, chemically-synthesized or recombinant proteins); and
 - 4. A statement that the antibody/ies were purified using either affinity purification or chromatographic purification methods; and
 - 5. A statement that the antibody/ies were not raised against antigens consisting of, or produced by, a pathogen of animal biosecurity concern for biological products (as published on the Department of Agriculture, Fisheries and Forestry website) or a disease agent causing a Listed Human Disease (as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases)* Determination 2016).

Date: 29 March 2023

h. Post entry/end use conditions

Permit: 0007494775 Page 37 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 38 of 81

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

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

13. Antibodies

13.1. 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

Permit: 0007494775 Page 39 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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.

Permit: 0007494775 Page 40 of 81

k. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.

1. 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.

Permit: 0007494775 Page 41 of 81

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

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

14. Antigens

14.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- a. The import permit covers the requirements for the importation of antigens derived from multicellular organisms (plants and animals) or synthetic (non-biological) material only. The import permit does not cover the requirements for the importation of whole microorganisms (both viable and non-viable) and antigens derived from microorganisms (which include viruses, bacteria and prions), or for the importation of antisera.
- b. This import permit does not cover the requirements for the importation of antigens which are suspended in animal blood products (sera).
- c. The goods are individually packaged in units of no greater than 20mL or 20g.

Import conditions after arrival in Australian territory

d. Post entry/end use conditions

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

OR

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

Additional information

e. Commercial administrative conditions

Documents must be provided with each consignment which:

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

Permit: 0007494775 Page 42 of 81



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

1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 43 of 81

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

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

15. Cell lines and/or supernatant fluid

15.1. 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.

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:

- 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.

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

Permit: 0007494775 Page 44 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 45 of 81

16. Cell lines from non-laboratory animals

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

16. Cell lines and/or supernatant fluid

16.1. 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:

- 1. a statement that the cell line has shown no signs of contamination, including cytopathic effects, with adventitious infectious agents or microbial contamination,
- 2. a statement that the cell line has not been inoculated with any live, or whole inactivated, microorganisms, viruses or prions (other than viral DNA which has been used to immortalise the cell line),
- 3. a statement that the cell line has not been inoculated with any derivatives of microorganisms, viruses or prions (other than viral DNA which has been used to immortalise the cell line).
- 4. either:
 - 4.1. a statement that the cell line is less than 2 years old and was derived from animals or humans with no history or clinical signs of infectious disease, or
 - 4.2. a statement that the cell line is greater than 2 years old.
- c. Additional conditions for cell lines and media derived from bovine, porcine, ovine, caprine, equine, avian or cervine animals, additional evidence must be presented to demonstrate freedom from disease.

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

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

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

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

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

Permit: 0007494775 Page 46 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, fees are payable to the Department of Agriculture,

Permit: 0007494775 Page 47 of 81

Fisheries and Forestry for all services. Detail on how the department applies fees and levies may be found in the <u>Charging guidelines</u>.

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.

Permit: 0007494775 Page 48 of 81

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

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

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

17.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- a. These import conditions allow for the import of culture media that contains no greater than 20ml or 20g of animal derived material in each individual unit.
- b. The goods must meet biosecurity requirements.

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

A statement that the goods:

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

Import conditions after arrival in Australian territory

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

Date: 29 March 2023

3. describe the goods being imported (where not clear). e.g. 1: Product XRab = Purified protein derived from rabbits Permit: 0007494775 Page 49 of 81

- 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. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 50 of 81

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

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

18. Genetic material

18.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- a. These conditions allow for the importation of purified genetic material (nucleic acids) derived from multicellular organisms (excluding plants and fungi).
- b. These conditions do NOT allow the importation of:
 - 1. Genetic material derived from microorganisms and infectious agents (including prions).
 - 2. Cloning vectors or expression systems.
 - 3. Genetic material derived from plants.
 - 4. Genetic material derived from fungi.
- c. The goods are individually packaged in units of no greater than 20mL or 20g.
- d. The goods must meet biosecurity requirements.

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

Evidence that:

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

Import conditions after arrival in Australian territory

e. Post entry/end use conditions

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

OR

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

Date: 29 March 2023

Additional information

Permit: 0007494775 Page 51 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 52 of 81

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

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

19. Genetic material

19.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- a. These conditions allow for the import of purified genetic material derived from, or homologous to sequences from, disease agents* excluding:
 - 1. <u>Pathogens of animal biosecurity concern for biological products</u>, as published on the Department of Agriculture, Fisheries and Forestry's website; and
 - 2. Disease agents causing <u>Listed Human Diseases</u>, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*; and
 - 3. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).
 - *Disease agent includes but is not limited to microorganism, parasite, virus, prion, plasmid or viroid.
- b. The goods are individually packaged in units of no greater than 20mL or 20g.
- c. The genetic material must not be derived from or homologous to sequences from any prion (whether naturally occurring, chemically synthesized or recombinant protein).
- d. The goods must meet biosecurity requirements.
 - To demonstrate compliance with this requirement you must present the following on a Product label, Invoice, Manufacturer's declaration, Exporter's declaration or Supplier's declaration:

Evidence that:

- 1. The genetic material has been highly purified and is unable to replicate, and
- 2. The genetic material is derived or homologous to sequences from disease agents, excluding pathogens of animal biosecurity concern for biological products (as published on the Department of Agriculture, Fisheries and Forestry's website), a disease agent causing a Listed Human Disease (as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination* 2016) or plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

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.

Permit: 0007494775 Page 53 of 81

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. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 54 of 81

20. Standard laboratory vectors for routine scientific purposes

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

20. Genetic material

20.1. Biosecurity Pathway



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

Import conditions prior to arrival in Australian territory

- a. The goods must be plasmids, cosmids, yeast artificial chromosomes, bacterial artificial chromosomes, *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors, and/or the following viral vectors only:
 - 1. Human immunodeficiency virus (HIV) vectors.
 - 2. Bacteriophages lambda, lambdoid and Ff.
 - 3. Polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV).
- b. The goods must be individually packaged in units of no greater than 20mL or 20g.
- c. The vectors must:
 - 1. have been deliberately constructed for a specific purpose such as cloning and expression or production of viral vectors,
 - 2. in the case of plasmids or cosmids be non-integrative and non-conjugative,
 - 3. in the case of viral vectors be replication incompetent or unable to produce a viral or infectious particle,
 - 4. not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions, and
 - 5. not contain nucleic acid derived from and/or associated with, or homologous to the following:
 - 1. <u>Pathogens of animal biosecurity concern for biological products</u> (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
 - 2. <u>Disease agents causing Listed Human Diseases</u>, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.
- d. The vectors must not contain the whole genome or a whole autonomous genomic region* of any organism other than sequences derived from or homologous to sequences from:
 - 1. Multicellular organisms (excluding fungi).
 - 2. Standard laboratory microorganisms and infectious agents (Appendix 3).
 - 3. Listed Department of Agriculture, Fisheries and Forestry approved starter cultures (Appendix 2).

Permit: 0007494775 Page 55 of 81

4. Vectors as described above.



Autonomous genomic regions are distinct nucleic acid sequences which can be replicated independently such as transposons, entire viral genomes, entire segments of a segmented viral genome, and natural plasmids.

A natural plasmid is a plasmid which naturally occurs in a bacterium, protozoan or a multicellular organism that has not been manipulated or genetically engineered.

- e. The vectors must not be designed to increase the following traits in the organisms they are transduced, transformed or introduced into (other than antibiotic resistance genes used to facilitate selection of the vector):
 - 1. Pathogenicity
 - 2. Virulence
 - 3. Ability to replicate and invade host cells
 - 4. Host range and/or susceptibility
 - 5. Increase mode of transmission to animals
 - 6. Ability to evade the host immune system
 - 7. Increased cytotoxic or oncogenic effects
- f. The proteins, coding regions, and genetic information included in any vectors must not be derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species.
- g. The product must not be on a whole seed, whole grain or animal derived carrier (other than lactose).
- h. The vectors may be imported in:
 - 1. Any microorganisms or virus listed in the standard laboratory microorganisms and infectious agents (Appendix 3).
 - 2. Any microorganism or virus listed in the approved starter cultures list (Appendix 2).
- i. The goods must meet biosecurity requirements.

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

- 1. A statement that the goods are plasmids, cosmids, yeast artificial chromosomes, bacterial artificial chromosomes, *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors, and/or the following viral vectors only:
 - 1.1. Human immunodeficiency virus (HIV) vectors.
 - 1.2. Bacteriophages lambda, lambdoid and Ff.
 - 1.3. Polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV).
- 2. A statement that the vectors:
 - 2.1. Have been deliberately constructed for the purpose of cloning and expression or production of viral vectors,
 - 2.2. In the case of plasmids or cosmids are non-integrative and non-conjugative.

Permit: 0007494775 Page 56 of 81

2.3. In the case of viral vectors are replication incompetent and unable to produce a viral or infectious particle.

- 2.4. Do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions.
- 2.5. Do not contain nucleic acid derived from and/or associated with, or homologous to the following:
 - Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
 - <u>Disease agents causing Listed Human Diseases</u>, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.
- 3. A statement that the vectors do not contain the whole genome or a whole autonomous genomic region* of any organism other than sequences derived from or homologous to sequences from:
 - 3.1. Multicellular organisms (excluding fungi), and/or
 - 3.2. Standard laboratory microorganisms and infectious agents (Appendix 3), and/or
 - 3.3. Listed Department of Agriculture, Fisheries and Forestry approved starter cultures (Appendix 2).
- 4. A statement that the vectors are not designed to increase the following traits in the organisms they are transduced, transformed or introduced into (other than antibiotic resistance genes used to facilitate selection of the vector):
 - 4.1. Pathogenicity.
 - 4.2. Virulence.
 - 4.3. Ability to replicate and invade host cells.
 - 4.4. Host range and/or susceptibility.
 - 4.5. Increase mode of transmission to animals.
 - 4.6. Ability to evade the host immune system.
 - 4.7. Increased cytotoxic or oncogenic effects.
- 5. A statement that the proteins, coding regions, and genetic information included in any vectors are not derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species, and
- 6. A statement that the product is not on a whole seed, whole grain or animal derived carrier (other than lactose).

Import conditions after arrival in Australian territory

- j. It is the importer's responsibility to ensure the import conditions are met and the goods (including derivatives) are only used in accordance with the following end use conditions.
- k. **Post entry/end use conditions**

Approved end uses:

- 1. in vitro laboratory studies, and
- 2. *in vivo* in laboratory organisms. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits, or microorganisms contained under laboratory or animal house conditions.
- 3. The culturing and isolation of microorganisms and infectious agents, including the following:

Permit: 0007494775 Page 57 of 81

3.1. Propagating microorganisms and infectious agents from the goods, and/or

3.2. inserting or inoculating microorganisms or infectious agents into eukaryotic or prokaryotic cell cultures.



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

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



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

- m. The goods must not deliberately be used in circumstances where recombination and reassortment events with any other virus could reasonably be expected to occur, including coinfection of animals or cell lines with related or homologous infectious agents.
- n. 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 the synthesis of replication-competent microorganisms, infectious agent or homologues beyond those outlined in the approved end uses, and
 - 5. for intentional co-culturing of virus vectors with related or homologous infectious agents.
- o. *For information on how to obtain additional written approvals contact imports@agriculture.gov.au or call 1800 900 090.

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



- 1. International (e.g. <u>International Air Transport Association</u>) 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.
- p. Imported material and derivatives are not to be used with genes derived from and/or associated with, or homologous to the following without further assessment by the Department of Agriculture, Fisheries and Forestry:

Permit: 0007494775 Page 58 of 81

1. Pathogens of animal biosecurity concern for biological products, as published on the Department of Agriculture, Fisheries and Forestry's website.

2. <u>Disease agents causing Listed Human Diseases</u>, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.

Additional information

q. 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.
- r. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- s. 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.

Permit: 0007494775 Page 59 of 81

21. Standard laboratory vectors for nucleic acid sequencing

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

21. Genetic material

21.1. Biosecurity Pathway



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

Import conditions prior to arrival in Australian territory

- a. These conditions allow for the importation of plasmids, cosmids, yeast artificial chromosomes, bacterial artificial chromosomes, *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors, and/or the following viral vectors only:
 - 1. Human immunodeficiency virus (HIV) vectors.
 - 2. Bacteriophages lambda, lambdoid and Ff.
 - 3. Polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV).
- b. The goods must be individually packaged in units of no greater than 20mL or 20g.
- c. The vectors must not contain nucleic acid derived from and/or associated with, and/or homologous to any of the following:
 - 1. <u>Pathogens of animal biosecurity concern for biological products</u> (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
 - 2. <u>Disease agents causing Listed Human Diseases</u>, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.
 - 3. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).
- d. The proteins, coding regions, and genetic information included in any vectors must not be derived from or homologous to prion protein (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species.
- e. Viral vectors must be replication incompetent or unable to produce a viral or infectious particle.
- f. The product must not be on a whole seed, whole grain or animal derived carrier (other than lactose).
- g. The vectors may be imported in:
 - 1. Any microorganisms or virus listed in the standard laboratory microorganisms and infectious agents (Appendix 3).
 - 2. Any microorganism or virus listed in the approved starter cultures list (Appendix 2).

Date: 29 March 2023

h. The goods must meet biosecurity requirements.

Permit: 0007494775 Page 60 of 81

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 goods are:
 - 1.1. Plasmids, cosmids, yeast artificial chromosomes and bacterial artificial chromosomes; and/or
 - 1.2. Bacteriophages lambda, lambdoid and Ff; and/or
 - 1.3. Human immunodeficiency virus (HIV) vectors, polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV); and/or
 - 1.4. Escherichia coli-Streptomyces artificial chromosome (ESAC) vectors; and
- 2. A statement that the goods do not contain nucleic acid derived from and/or associated with, or homologous to the following:
 - 2.1. <u>Pathogens of animal biosecurity concern for biological products</u> (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
 - 2.2. <u>Disease agents causing Listed Human Diseases</u>, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.
 - 2.3. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

Import conditions after arrival in Australian territory

- i. It is the importer's responsibility to ensure the import conditions are met and the goods (including derivatives) are only used in accordance with the following end use conditions.
- j. Post entry/end use conditions
 - 1. The goods must be used for nucleic acid sequencing only.
 - 2. The goods must not be exposed to or used in animals, plants, microorganisms, cell cultures or the environment, and must not be used in or on humans.
 - 3. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.
 - 4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

OR

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

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



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

Additional information

1. Commercial administrative conditions

Documents must be provided with each consignment which:

Permit: 0007494775 Page 61 of 81

- 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.



- 1. International (e.g. <u>International Air Transport Association</u>) and domestic requirements concerning the safe handling, transport and labelling of biological material
- 2. AS/NZS 2243 Safety in Laboratories standards
- 3. Office of the Gene Technology Regulator (OGTR) requirements
- 4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.
- m. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- n. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

Permit: 0007494775 Page 62 of 81

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

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

22. Microorganisms (including viruses)



Some products may require specialised storage and/or handling.

22.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- a. The product must be on the list of standard laboratory microorganisms and infectious agents. Please refer to the standard laboratory microorganisms and infectious agents (Appendix 3) list.
- b. Derivatives must be primary derivatives i.e. components that have been directly isolated and purified from a pure culture of the microorganism. Secondary derivatives i.e. components of the microorganism that have undergone passage or inoculation into a second organism e.g. antibodies, are not permitted under these import conditions.
 - Derivatives must be imported in quantities of no greater than 20ml or 20g for each individually packaged unit.
- c. Microorganisms and infectious agents may be imported on a non-biological matrix (e.g. biological indicators, spore strips).
- d. Each culture, derivative, sequence or vector must be clearly identified.
 - To demonstrate compliance with this requirement you must present the following on a Product label, Invoice, Manufacturer's declaration, Exporter's declaration or Supplier's declaration:

The scientific name of the microorganism or the source microorganism of derivatives, sequences and vectors.

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

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

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.

Date: 29 March 2023

2. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

Permit: 0007494775 Page 63 of 81

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 64 of 81

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

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

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

23.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- a. These conditions allow for the import of prepared microbiological culture media that is prepackaged and ready for use by the end user including:
 - 1. plates e.g. petri dishes containing media
 - 2. swabs e.g. transport swabs
 - 3. dip slides
 - 4. vials, and/or
 - 5. tubes (including slopes).
- b. The goods must contain no greater than 50 mL or 50 g of media per individually packaged unit.
- c. The goods must be sterilised prior to arrival in Australian territory.
- d. The goods must not be or contain foetal bovine serum (FBS).
- e. The goods must meet biosecurity requirements.

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

A statement that the goods:

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

Import conditions after arrival in Australian territory

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

OR

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

Permit: 0007494775 Page 65 of 81



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

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

Additional information

g. Commercial administrative conditions

Documents must be provided with each consignment which:

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



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

- 1. International (e.g. <u>International Air Transport Association</u>) and domestic requirements concerning the safe handling, transport and labelling of biological material
- 2. AS/NZS 2243 Safety in Laboratories standards
- 3. Office of the Gene Technology Regulator (OGTR) requirements
- 4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.
- h. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, fees are payable to the Department of Agriculture, Fisheries and Forestry for all services. Detail on how the department applies fees and levies may be found in the Charging guidelines.
- i. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

Permit: 0007494775 Page 66 of 81

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

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

24. Purified laboratory reagents, toxins and venoms

24.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

- 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. recombinant proteins and peptides (excluding prions)
 - 11. lipids (includes fats, waxes, sterols, glycerides, phospholipids and their derivatives)
 - 12. co-factors
 - 13. other proteins (including derivatives e.g. peptides) not listed under any of the categories 1-10 above, excluding:
 - 13.1. prions (derived from an organism, recombinant protein, or synthetic)
 - 13.2. antibodies
 - 13.3. proteins (including derivatives e.g. peptides) derived from:
 - 13.3.1. <u>Pathogens of animal biosecurity concern for biological products</u>, as published on the department's website
 - 13.3.2. Disease agents causing <u>Listed Human Diseases</u>, as published on the Department of Health and Aged Care'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.

Permit: 0007494775 Page 67 of 81

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, Fisheries and Forestry's website) or a disease agent causing a Listed Human Disease (as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*).

Import conditions after arrival in Australian territory

f. Post entry/end use conditions

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

OR

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

Additional information

g. Commercial administrative conditions

Documents must be provided with each consignment which:

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



- 1. International (e.g. <u>International Air Transport Association</u>) 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

Permit: 0007494775 Page 68 of 81

- 4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.
- h. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 69 of 81

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

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

25. Soil and water samples

25.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. The goods must meet biosecurity requirements.

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

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

Import conditions after arrival in Australian territory

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

c. Post entry/end use conditions

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

OR

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



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

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

Date: 29 March 2023

- 2. *in vivo* in non-laboratory organisms e.g. chickens, sheep, cattle
- 3. in plants
- 4. in culturing or isolating microorganisms and infectious agents.

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

Additional information

d. Commercial administrative conditions

Documents must be provided with each consignment which:

Permit: 0007494775 Page 70 of 81

- 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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 71 of 81

26. Nucleic Acid Amplification (NAA) test kits

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

26. Test kits

26.1. Biosecurity Pathway



These conditions allow for the import of:

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



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

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

Import conditions prior to arrival in Australian territory

a. The goods must meet biosecurity requirements.

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

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

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

b. The goods must be commercially manufactured and packaged.

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, plants, microorganisms, cell cultures or the environment, and must not be used in or on humans (except for allergy tests to be applied to the skin).
- 2. The goods must not be 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.

Permit: 0007494775 Page 72 of 81

4. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.

5. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

OR

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

Additional information

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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 <u>Australian Pesticide and Veterinary</u> Medicines Authority (APVMA).
- 6. The Security Sensitive Biological Agents (SSBA) regulatory scheme.
- e. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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.

Permit: 0007494775 Page 73 of 81

27. Test kits not testing for disease agents

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

27. Test kits

27.1. Biosecurity Pathway



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

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



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

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

Import conditions prior to arrival in Australian territory

- a. The goods must only be test kits, which:
 - 1. do not test for disease agents.
 - 2. do not contain disease agents (live, live attenuated or inactivated) or their derivatives (e.g. antigens).
 - 3. do not contain any components raised against disease agents (e.g. antibodies).
- b. All animal derived material must be in volumes of no greater than 20ml or 20g per individually packaged unit.

Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained within must not be greater than 20ml or 20g.

- c. The goods must be commercially manufactured and packaged.
- d. The goods must meet biosecurity requirements.

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

1. A statement that the goods are test kits (or individual components specifically designed for use with kits eligible for import under these conditions), which:

- 1.1. do not test for disease agents.
- 1.2. do not contain disease agents (live, live attenuated, or inactivated) or their

Permit: 0007494775 Page 74 of 81

derivatives (e.g. antigens).

1.3. do not contain any components raised against disease agents (e.g. antibodies).

2. A statement that all animal derived material contained in these test kit(s) is in volumes of no greater than 20ml or 20g per individually packaged unit.

Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained within must not be greater than 20ml or 20g.

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

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, plants, microorganisms, cell cultures or the environment, and must not be used in or on humans (except for allergy tests to be applied to the skin).
- 2. The goods must not be 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.

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.



- 1. International (e.g. <u>International Air Transport Association</u>) 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.

Permit: 0007494775 Page 75 of 81

4. Any regulatory requirements of the Therapeutic Goods Administration (TGA).

- 5. Any regulatory requirements of the <u>Australian Pesticide and Veterinary Medicines Authority (APVMA)</u>.
- 6. The Security Sensitive Biological Agents (SSBA) regulatory scheme.
- g. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, 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 <u>Charging guidelines</u>.
- 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.

Permit: 0007494775 Page 76 of 81

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.

Permit: 0007494775 Page 77 of 81

Appendix 2: List: Approved starter cultures

List of approved starter cultures

List of approved starter culture	28	1
Acetobacter spp.	Aspergillus brasiliensis	Aspergillus oryzae
Aspergillus niger	Bacillus acidopullulyticus	Bacillus amyloliquefaciens
Bacillus coagulans	Bacillus halodurans	Bacillus licheniformis
Bacillus subtilis	Baker's yeast	Bifidobacterium spp.
Brevibacterium linens	Brewer's yeast	Candida spp.
Chaetomium gracile	Citeromyces spp.	Clavispora spp.
Debaryomyces spp.	Dekkera spp.	Enterococcus durans
Enterococcus faecalis	Enterococcus faecium	Geotrichum candidum
Hansenula spp.	Hasegawaea spp.	Humicola insolens
Hyphopichia spp.	Issatchenkia spp.	Kluyveromyces spp.
Lactic acid bacteria	Lactobacillus spp.	Lactococcus spp.
Leuconostoc spp. (Oenococcus spp.)	Monascus spp.	Pediococcus pentosaceus
Penicillium camemberti (also known as Penicillium camembertii and Penicillium candidum)	Penicillium funiculosum	Penicillium roqueforti (also known as Penicillium roquefortii)
Phaffia spp.	Pichia spp.	Propionibacterium spp.
Rhizopus spp.	Saccharomyces spp.	Schizosaccharomyces spp.
Schwanniomyces spp.	Staphylococcus carnosus	Staphylococcus xylosus
Streptococcus cremoris	Streptococcus diacetilactis	Streptococcus durans
Streptococcus faecalis	Streptococcus lactis	Streptococcus salivarius
Streptococcus thermophilus	Streptomyces olivaceus	Streptomyces olivochromogenes
Streptomyces murinus	Streptomyces mobaraensis (former name Streptoverticillium mobaraensis)	Streptomyces rubiginosus
Streptomyces violaceoruber	Talaromyces emersonii (former name Penicillium emersonii)	Torulaspora spp.
Torulopsis spp.	Trichoderma harzianum	Trichoderma reesei (former name Trichoderma longibrachiatum)
Trichoderma viride	Wine culture	Yoghurt/Kefir culture
Zygoascus spp.	Zygosaccharomyces spp.	

Permit: 0007494775 Page 78 of 81

Appendix 3: List: Standard laboratory microorganisms and infectious agents

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

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

Permit: 0007494775 Page 79 of 81

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

Permit: 0007494775 Page 80 of 81

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

Permit: 0007494775 Page 81 of 81

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

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