

Permit to import conditionally non-prohibited goods

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

Permit: 0006450256

Valid for: multiple consignments

between 17 June 2022 and 17 June 2024

This permit is issued to: Neogen Australasia Pty Limited

14 Hume Drive

BUNDAMBA QLD 4304

Australia

Attention: Ms Deanne Waine

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

Exporter details: Various exporters

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

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

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

Country of export: Various countries Various countries

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

sourced from bovines only

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

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

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

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

sourced from camelids only Page 7

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 ovines and caprines only

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: 17 June 2022

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

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

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

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

sourced from suids (porcines) only

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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: Salmonidae (salmon) fish fluids and tissues (excluding

reproductive material)

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

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

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

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

from species, other than those excluded

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7. Microorganisms (including viruses)

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

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

Permit Conditions: Standard laboratory microorganisms and infectious agents

(and derivatives)

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 -----

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Important information about this permit and the import of goods

Note: This permit covers Department of Agriculture, Water and the Environment 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, Water and the Environment for all imported goods other than goods imported as accompanied baggage or goods imported via the mail and not prescribed under *the Customs Act* 1901, 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, Water and the Environment 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, Water and the Environment 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, Water and the Environment". 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, Water and the Environment's <u>minimum</u> <u>documentation requirements policy</u>.

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, Water and the Environment 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.

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Permit conditions

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

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

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

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

1.1. Biosecurity Pathway

a. Source species and countries

The goods must be fluids and tissues sourced from 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.

Date: 17 June 2022

[The declaration must indicate the option that applies].

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

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

e. Post entry/end use conditions

Approved end uses:

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

These conditions do not permit:

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

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



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

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

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



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

- 1. International (e.g. <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. Commercial administrative conditions

- 1. identify the consignment (if non-personal) e.g. entry number
- 2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
- 3. describe the goods being imported (where not clear).
 - e.g. 1: Product XRab = Purified protein derived from rabbits
 - e.g. 2: Product AX = Synthetic antibiotic
 - e.g. 3: Comte = Cheese.
- g. Under the <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, Water and the Environment for all services. Detail on how the department applies fees and levies may be found in the <u>Charging guidelines</u>.

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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.

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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

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

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

e. Post entry/end use conditions

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Approved end uses:

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

These conditions do not permit:

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

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



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

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

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



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

- 1. International (e.g. <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. Commercial administrative conditions

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

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

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

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

3.1. Biosecurity Pathway

a. Source species and countries

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

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

e. Post entry/end use conditions

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Approved end uses:

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

These conditions do not permit:

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

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



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

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

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



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

- 1. International (e.g. <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. Commercial administrative conditions

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

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

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

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

4.1. Biosecurity Pathway

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

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

e. Post entry/end use conditions

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Approved end uses:

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

These conditions do not permit:

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

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



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

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

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



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

- 1. International (e.g. <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. Commercial administrative conditions

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

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

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

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

5.1. Biosecurity Pathway

a. Source species

The goods must be fluids and tissues sourced from Salmonidae (salmon) species (Appendix $\underline{1}$) only.

b. The goods must meet biosecurity requirements.

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

i. Sourcing

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

AND

ii. Animal Health

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

[The declaration must indicate the option that applies].

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

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

e. Post entry/end use conditions

Approved end uses:

1. *in vitro* laboratory studies, and/or

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

These conditions do not permit:

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

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



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

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

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



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. Commercial administrative conditions

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

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

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

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

6.1. Biosecurity Pathway

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

e. 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.

f. Post entry/end use conditions

Approved end uses:

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

These conditions do not permit:

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

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

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

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

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



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

- 1. International (e.g. <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. Commercial administrative conditions

Documents must be provided with each consignment which:

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

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

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

7. Microorganisms (including viruses)



Some products may require specialised storage and/or handling.

7.1. Biosecurity Pathway

- a. The product must be on the list of standard laboratory microorganisms and infectious agents. Please refer to the standard laboratory microorganisms and infectious agents (Appendix 3) list.
- b. Derivatives must be primary derivatives i.e. components that have been directly isolated and purified from a pure culture of the microorganism. Secondary derivatives i.e. components of the microorganism that have undergone passage or inoculation into a second organism e.g. antibodies, are not permitted under these import conditions.
 - Derivatives must be imported in quantities of no greater than 20ml or 20g for each individually packaged unit.
- c. Importation of the following is permitted:
 - 1. Nucleic acid sequences directly isolated from or identical to any standard laboratory microorganisms and infectious agents (Appendix 3) may also be imported in purified standard laboratory cloning vectors and expression vectors as described in point 3. below, or as linear nucleic acid fragments.
 - 2. The microorganisms listed may also contain standard laboratory cloning vectors and expression vectors as listed and as described in point 3. below. These standard cloning and expression vectors may include nucleic acid from the organisms listed below in addition to the nucleic acid backbone:
 - 2.1. Multicellular organisms (excluding plants or fungi), or
 - 2.2. any microorganism/s and viruses in the standard laboratory microorganisms and infectious agents list
 - 3. Permitted purified standard laboratory cloning and expression vectors are:
 - 3.1. Plasmids, cosmids, yeast and bacterial artificial chromosomes, which have been deliberately constructed for that purpose which are non-integrative and non-conjugative, and do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions, or which contain known autonomous genetic elements from any species, or "pathogenicity islands" or known bacterial virulence factors excluding antimicrobial resistance genes used to facilitate selection and plasmid replication factors; and
 - 3.2. Human immunodeficiency virus (HIV) vectors, bacteriophages lambda, lambdoid and Ff, polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV). No other viral vectors are permitted; and
 - 3.3. Escherichia coli-Streptomyces artificial chromosome (ESAC) vectors.
- d. Microorganisms and infectious agents may be imported on a non-biological matrix (e.g. biological indicators, spore strips).

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e. Each culture, derivative, sequence or vector must be clearly identified.

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

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

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

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

f. Post entry/end use conditions

Approved end uses:

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

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

- 1. in plants,
- 2. in non-laboratory organisms e.g. chickens, sheep, cattle,
- 3. as veterinary vaccines and therapeutics.
- * For information on how to obtain additional written approvals contact imports@awe.gov.au or call 1800 900 090.

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



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

- 1. International (e.g. <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. Commercial administrative conditions

- 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

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- 3. describe the goods being imported (where not clear).
 - e.g. 1: Product XRab = Purified protein derived from rabbits
 - e.g. 2: Product AX = Synthetic antibiotic
 - e.g. 3: Comte = Cheese.
- h. Under the <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, Water and the Environment 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.

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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.

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Appendix 2: List: Approved starter cultures

List of approved starter cultures

List of approved starter culture	es	
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
<i>Hyphopichia</i> 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.	

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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

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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	Entomophthora anisopliae	Erwinia tasmaniensis
Escherichia spp.	Ferroplasma spp.	Fusarium venenatum	Geobacillus spp.
Geobacter spp.	Giardia spp.	Gigaspora margarita	Gliocadium catenalatum
Haemophilus spp.	Human Adenovirus Types 1-51	Human coxsackieviruses 1-24	Human echovirus 1-33
Human hepatitis virus A, B, C, D, E, G &TTV	Human Herpes virus 1-8 (includes Herpes simplex virus 1 and 2, Varicella zoster, Epstein-Barr virus and Cytomegalovirus)	Human immunodeficiency virus (HIV)	Human noroviruses
Human papilloma virus	Human respiratory syncytial virus	Human rhinovirus	Isochrysis galbana
Klebsiella spp.	Legionella spp.	Leptospira copenhageni (Leptospira interrogans serovar Copenhageni)	Leptospira gripptotyphosa (Leptospira interrogans serovar Gripptotyphosa)
Leptospira hardjobovis (Leptospira borgpetersenii serovar hardjo-bovis)	Leptospira icterohaemorrhagiae (Leptospira interrogans serovar Icterohaemorrhagiae)	Leptospira pomona (Leptospira interrogans serovar Pomona)	Leptospirillum spp.
Listeria spp.	Magnetospirillum spp. (formerly Aquaspirillum spp.)	Metapneumovirus (human)	Metarhizium acridum
Metarhizium anisopliae var. anisopliae	Methanococcus spp.	Microtetraspora viridis	Moraxella spp. (includes subgen. Branhamella and subgen. Moraxella) (excluding M. anatipestifer)

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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

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Vaccinia virus (cow pox)		(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