Australian Government
Department of Agriculture,
Fisheries and Forestry

Permit to import conditionally non-prohibited goods

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

Permit: 0008399111

Valid for: multiple consignments between 13 February 2024 and 13 February 2029

This permit is issued to: SydPath
Level 6 Xavier Building
St Vincent's Hospital
Victoria St
Darlinghurst NSW 2010
AUSTRALIA

Attention: Mrs Lilian Milis

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. 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 4
2. Antibodies		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Purified antibodies raised against inorganic or multicellular antigens (Standard Permit)	Page 6
3. 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 8

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

Amy Wythes
Delegate of the Director of Biosecurity Date: 29 November 2023

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) from species, other than those excluded	Page 10
5. Genetic material		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Standard laboratory vectors for routine scientific purposes	Page 13
6. 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 18
7. Genetic material		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Standard laboratory vectors for nucleic acid sequencing	Page 20
8. 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 23
9. Antibodies		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Antibodies produced in recombinant systems or raised against recombinant antigens (Standard Permit)	Page 25

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

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

Important information about this permit and the import of goods

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

Information about this permit

Authority to import

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

Compliance with permit conditions and assessment and management of biosecurity risk

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

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

Change of import conditions

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

General information about importing goods

Notification of import

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

Provision of required documentation

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

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

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

Non-commodity cargo clearance

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

Fees

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

Compliance with other regulatory provisions

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

Permit conditions

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

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

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

1.	Genetic material

1.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

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

b. These conditions do NOT allow the importation of:

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

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

d. The goods must meet biosecurity requirements.

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

Evidence that:

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

Import conditions after arrival in Australian territory

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

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

OR

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

Additional information

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

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

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

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

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

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

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

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

2. Antibodies

2.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

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

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

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

b. The antibodies must not be suspended in whole blood, sera, plasma, ascitic fluid or culture supernatant fluid.

c. The antibodies must not be raised against any prion (whether naturally occurring, chemically synthesized or recombinant protein) from any species.

d. The antibodies may be conjugated to chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.

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

f. The goods must meet biosecurity requirements.

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

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

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

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

Import conditions after arrival in Australian territory

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

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

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

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

   OR

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

Additional information

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

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

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

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

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

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

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

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

3.	Human fluids and tissues

3.1. 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
3. describe the goods being imported (where not clear).
   e.g. 1: Product XRab = Purified protein derived from rabbits
   e.g. 2: Product AX = Synthetic antibiotic
   e.g. 3: Comte = Cheese.

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

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

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

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

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

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

The goods must not be reproductive material.

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

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

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

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

Antisera may only be raised against:

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

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

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

e. The goods must meet biosecurity requirements.

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

i. **Sourcing**

1. A statement that the goods are animal fluids and tissues only.
2. A statement that the goods have not been soured from avians, bovines, camelids, caprines, cervines, equines, giraffids, ovines, prawns, primates, suids (porcines) or Salmonidae fish.
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].

f. The goods must meet biosecurity requirements

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

Packaging

A statement that the goods are either:

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

[The declaration must indicate the option that applies].

Import conditions after arrival in Australian territory

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

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

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

   OR

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

Additional information

i. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer’s manifest

3. describe the goods being imported (where not clear).
   e.g. 1: Product XRab = Purified protein derived from rabbits
   e.g. 2: Product AX = Synthetic antibiotic
   e.g. 3: Comte = Cheese.

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

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

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

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

5. Standard laboratory vectors for routine scientific purposes

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

5.	Genetic material

5.1. 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. Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
      2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.

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 1).
   3. Listed Department of Agriculture, Fisheries and Forestry approved starter cultures (Appendix 2).

4. Vectors as described above.

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

e. The vectors must not be designed to increase the following traits in the organisms they are transduced, transformed or introduced into (other than antibiotic resistance genes used to facilitate selection of the vector):

1. Pathogenicity
2. Virulence
3. Ability to replicate and invade host cells
4. Host range and/or susceptibility
5. Increase mode of transmission to animals
6. Ability to evade the host immune system
7. Increased cytotoxic or oncogenic effects

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

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

h. The vectors may be imported as purified genetic material, or may be imported in:

1. Any microorganisms or virus listed in the standard laboratory microorganisms and infectious agents (Appendix 1).
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.

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

2.4. Do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions.

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

- Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
- Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.

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 1), 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**

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

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

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

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

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

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

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

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

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

Additional information

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

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

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

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

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

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

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

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

6.	Genetic material

6.1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

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

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

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

   OR

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

Additional information

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

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

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

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

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

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

7. Standard laboratory vectors for nucleic acid sequencing

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

7.	Genetic material

7.1. 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. Pathogens of animal biosecurity concern for biological products (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
   2. Disease agents causing Listed Human Diseases, as legislated under the *Biosecurity (Listed Human Disease) Determination 2016* and published on the Federal Register of Legislation.
   3. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

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

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

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

g. The vectors may be imported as purified genetic material, or may be imported in:
   1. Any microorganisms or virus listed in the standard laboratory microorganisms and infectious agents (Appendix 1).
   2. Any microorganism or virus listed in the approved starter cultures list (Appendix 2).

h. The goods must meet biosecurity requirements.

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

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

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

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

Import conditions after arrival in Australian territory

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

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

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

   OR

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

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

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

Additional information

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

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

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

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

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

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

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

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

8.	Antibodies

8.1. Biosecurity Pathway

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

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

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

Import conditions prior to arrival in Australian territory

b. The antibodies must not be suspended in whole blood, sera, plasma or ascitic fluid.

c. The antibodies must not be raised against any prion (whether naturally occurring, chemically synthesized or recombinant protein) from any species.

d. The antibodies must be purified using either affinity purification or chromatographic purification methods.

e. The antibodies may be conjugated to chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.

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

g. The goods must meet biosecurity requirements.

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

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

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

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

   OR

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

Additional information

i. **Commercial administrative conditions**

Documents must be provided with each consignment which:

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

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

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

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

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

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

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

9.	Antibodies

9.1. Biosecurity Pathway

a. This import permit covers the requirements for the importation of purified antibodies that are either:

1. antibodies produced without an immune response using a recombinant DNA expression system; or
2. antibodies raised against antigens produced using a recombinant DNA expression system, excluding antigens produced using a recombinant DNA expression system encoding whole genome segments of any virus or viroid.

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

Import conditions prior to arrival in Australian territory

b. The antibodies must not be suspended in whole blood, sera, plasma or ascitic fluid.

c. The antibodies must not be raised against any prion (whether naturally occurring, chemically synthesized or recombinant protein) from any species.

d. The antibodies must be purified using either affinity purification or chromatographic purification methods.

e. The antibodies may be conjugated to a protein, other than prion protein, produced using a recombinant DNA expression system.

f. The antibodies may be conjugated to chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.

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

h. The goods must meet biosecurity requirements.

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

1. The name of each antibody; and
2. The name of the antigen for each antibody; and

3. A statement that the antibody/ies were not raised against any prions (whether naturally-occurring, chemically-synthesized or recombinant protein); and
4. A statement that each antibody was purified using either affinity purification or chromatographic purification methods only; and
5. The following statement(s) where they apply:

   5.1. A statement that the antibody/ies are produced without an immune response using a recombinant DNA expression system; or
   5.2. A statement that the antibody/ies are raised against antigens produced using a recombinant DNA expression system, excluding antigens produced using a recombinant DNA expression system encoding whole genome segments of any virus or viroid.

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

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

   OR

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

Additional information

j. **Commercial administrative conditions**

Documents must be provided with each consignment which:

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

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

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

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

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

Appendix 1: 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.

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*

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)*	*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)*

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*

Vaccinia virus (cow pox)	*Vibrio alginolyticus*	*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*

Appendix 2: List: Approved starter cultures

List of approved starter cultures

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.	

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