Australian Government
Department of Agriculture

Permit to import conditionally non-prohibited goods

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

Permit: 0003617477

Valid for: multiple consignments between 12 October 2019 and 12 October 2021

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

Attention: Dr Pearl Tan

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

Exporter details:	Various exporters

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

1. Human fluids and tissues		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Human fluids and tissues that are not known to be infected	Page 4
2. Animal fluids and tissues (ex 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:	Low risk animal fluids and tissues excluding reproductive material	Page 6
3. Animal fluids and tissues (ex 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 from ovines, caprines, bovines, cervines, camelids and giraffids only	Page 8

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

Van Diep
Delegate of the Director of Biosecurity Date: 06 September 2019

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agriculture.gov.au
ABN 24 113 085 695

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

Authority to import

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

Compliance with permit conditions and freedom from contamination

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

Compliance with other regulatory provisions

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

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

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

Change of import conditions

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

Notification of import

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

Valid import permit

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

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

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

OR

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

Provision of required documentation

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

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

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

Permit conditions

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

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

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

1.	Human fluids and tissues

1.1. Biosecurity Pathway

a. **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.

b. Human fluids and tissues may not be imported for the purpose of screening for the following infectious diseases:

1. Highly pathogenic avian influenza (human)
2. Human swine influenza with pandemic potential
3. Middle East respiratory syndrome
4. Plague
5. Rabies
6. Severe acute respiratory syndrome (SARS)
7. Smallpox
8. Viral haemorrhagic fevers of humans
9. Yellow fever (in Northern Australia)
10. Any disease that is exotic to Australia

c. There is no requirement for a manufacturer or importer declaration to accompany samples imported into Australian territory.

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

1. These conditions allow for the importation of human fluids and tissues, not known to be infected, for *in vitro* laboratory studies (or *in vivo* use in laboratory organisms) only.
2. Laboratory organisms are those defined in the following list and must be contained under laboratory or animal house conditions: guinea pigs, hamsters, mice, rats, rabbits, or micro-organisms. Work in all other animals and plants is not permitted.
3. These conditions do not permit the direct or indirect exposure of the imported materials or derivatives to non-laboratory organisms or plants.
4. It is the end user's responsibility to ensure that the goods adhere to any Therapeutic

Goods Association (TGA) regulatory requirements.

5. It is the importer's responsibility to ensure that the goods are labelled '*in vitro* use or *in vivo* use in laboratory organisms only' or equivalent on the smallest packaged unit prior to distribution.
6. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243.3:2010 Safety in Laboratory Standards.
7. The importer must undertake a risk assessment to ensure any specific hazards associated with *in vitro* use or *in vivo* use in laboratory animals are managed using appropriate work practices including use of any standard precautions as outlined in the Australian Guidelines for the prevention and Control of Infection in Healthcare.
8. It is the end user's responsibility to ensure that all products are used in accordance with the Office of the Gene Technology Regulator (OGTR) and Therapeutic Goods Administration (TGA) requirements.
9. It is the importer's responsibility to ensure compliance with all international (e.g. International Air Transport Association (IATA)) and domestic requirements concerning the safe handling, transport and labelling of biological material.

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

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

2. Low risk animal fluids and tissues excluding reproductive material

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

2.	Animal fluids and tissues (ex reproductive material)

2.1. Biosecurity Pathway

a. The following conditions apply to:

1. animal fluids and tissues sourced from all species (excluding prawns, salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 20 mL or 20 g per individually packaged unit.
2. antisera sourced from all species (excluding prawns, salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 20 mL or 20 g per individually packaged unit. The antisera must only be raised against synthetic material or against antigens derived from multicellular organisms.
3. sera, plasma and blood proteins sourced from all species (excluding prawns, salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 20 mL or 20 g per individually packaged unit.
4. urine sourced from all species (excluding prawns, salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids), not knowingly infected; if imported in quantities of no greater than 500 mL or 500 g per individually packaged unit.
5. animal fluids (excluding reproductive material) sourced from all species and dried onto filter paper.

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

Approved end uses:

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

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

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

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

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

products may be labelled post entry.

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

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

c. **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.

d. 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 for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.

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

3. Animal fluids and tissues from ovines, caprines, bovines, cervines, camelids and giraffids only

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

3. Animal fluids and tissues (ex reproductive material)

3.1. Biosecurity Pathway

a. The following conditions apply to:

1. fluids and tissues (excluding reproductive material) sourced from ovines, caprines, bovines, cervines, camelids and giraffids.
2. antisera derived from these species. The antisera must only be raised against synthetic material or against antigens derived from multicellular organisms. Antisera raised against microorganisms (including viruses and prions) are not permitted under these conditions.
3. sera, plasma and blood proteins from these species.
4. urine sourced from these species if imported in quantities of no greater than 500 mL or 500 g per individually packaged unit.

b. The product must be sourced from animals not knowingly infected.

c. The product must be sourced from animals born, raised and residing in one of the following countries:
Australia, Austria, Belgium, Canada, Chile, Cyprus, Czechia (Czech Republic), Denmark, Estonia, France, Finland, Germany, Hungary, Iceland, Indonesia, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Iceland, Malta, Mexico, Netherlands, New Caledonia, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States of America, Vanuatu.

If the product is not sourced from one of the countries listed above it must be subjected to gamma irradiation at 50 kGy (5 Mrad) before it is released to the importer. Irradiation at 50 kGy at a Department of Agriculture approved facility is mandatory even if the product has been irradiated prior to import into Australian territory.

d. The products (other than urine) must be imported in quantities of no greater than 20 mL or 20 g for each individually packaged unit.

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.

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

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

homologues

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

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

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

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

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).
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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 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.

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