Australian Government
Department of Agriculture

Permit to import conditionally non-prohibited goods
This permit is issued under *Biosecurity Act 2015* Section 179 (1)

Permit: 0003853186

Valid for: multiple consignments between 6 January 2020 and 6 January 2022

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. Purified laboratory reagents, toxins and venoms		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Purified laboratory material, laboratory reagents, toxins and venoms	Page 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:	Antibodies purified and raised against synthetic material or antigens from multicellular organisms	Page 7
3. Cell lines and/or supernatant fluid		
End use:	In vitro use or in vivo use in laboratory organisms	
Country of export:	Various countries	
Country of origin:	Various countries	
Permit Conditions:	Cell lines of laboratory animal, insect and human origin	Page 9

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: 26 November 2019

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18 Marcus Clarke Street
Canberra City ACT 2601
GPO Box 858
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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. Purified laboratory material, laboratory reagents, toxins and venoms

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

1.	Purified laboratory reagents, toxins and venoms

1.1. Biosecurity Pathway

a. These conditions allow for the import of the listed purified laboratory material / laboratory reagents:

1. albumins, (including bovine serum albumin (BSA))
2. antibiotics (e.g. antibiotic sensitivity discs)
3. co-factors
4.enzymes
5. enzyme inhibitors
6. growth factors
7. hormones
8. laboratory material derived from a fermentation process
9. lipids (includes fats, waxes, sterols, glycerides phospholipids and their derivatives)
10. proteins (including derivatives e.g. peptides) excluding prions.
11. purified toxins
12. purified venoms

The above must be derived from one of the following sources only:

1. animals; or
2. a fermentation process; or
3. bacteria (including recombinant bacteria); or
4. fungi

b. The products must be imported in quantities of no greater than 20ml or 20g for each individually packaged unit.

c. 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:

i. 1. A statement that the product does not contain ingredients of animal, plant or microbial origin, other than <<*name of product/s*>>, and
2. Evidence that the product/s are in quantities of no greater than 20ml or 20g for each individually packaged unit.

OR

ii. 1. Details of a full list of ingredients totalling 100%, and
2. Evidence that the product/s are in quantities of no greater than 20ml or 20g for each individually packaged unit.

d. **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.

Security Sensitive Biological Agents (SSBA)

Abrin, ricin and botulinum toxins are classified as Security Sensitive Biological Agents (SSBA) under the National Health Security Act 2007 and the National Health Security Regulations 2008. Australian entities wishing to import these toxins are advised to contact the DHA website for further information regarding their statutory obligations prior to importing the SSBA:

Laboratory Capacity and Regulation Section
Department of Health
GPO Box 9848,
Canberra ACT 2601

Switchboard: +61 2 6289 1555

Freecall (within Australia): +61 1800 020 103

Email: ssba@health.gov.au

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

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

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

   e.g. 2: Product AX = Synthetic antibiotic

   e.g. 3: Comte = Cheese.

f. 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.

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

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

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

2.	Antibodies

2.1. Biosecurity Pathway

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

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

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

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

d. The products must be imported in quantities of no greater than 20ml or 20g for each individually packaged unit.

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

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

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

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

Approved end uses:

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

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

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

*For information on how to obtain additional written approvals contact imports@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.

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

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

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

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

3.	Cell lines and/or supernatant fluid

3.1. Biosecurity Pathway

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

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

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

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

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

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

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

Approved end uses:

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

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

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

* For information on how to obtain additional written approvals contact imports@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.

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

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

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