

#### Permit to import conditionally non-prohibited goods

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

Permit: 0001961394

Valid for: multiple consignments

between 11 January 2018 and 12 September 2018

This permit is issued to: Australian Nuclear Science and Technology Organisation

Australian Synchrotron 800 Blackburn Road Clayton VIC 3168

Australia

Attention: Mrs Clare Scott

#### 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 or refined laboratory reagents

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/refined laboratory reagents Page 5

2. Untanned hides and skins

End use: All end uses other than animal feeds, fertilisers and growing purposes

Country of export: New Zealand Country of origin: New Zealand

Permit Conditions: Untanned hides and skins Page 8

3. Cell lines and/or supernatant fluid

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

Country of export: Various countries

Permit Conditions: Cell lines of laboratory animal and human origin Page 10

4. Cell lines and/or supernatant fluid

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

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

Craig Cal

Delegate of the Director of Biosecurity Date: 11 January 2018

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

Permit Conditions: Cell lines from non-laboratory animals Page 12

5. 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 15

6. 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 17

7. 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 excluding reproductive material

sourced from porcines only Page 19

8. 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 excluding reproductive material

sourced from equines only Page 22

9. 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 excluding reproductive material

sourced from avians only Page 25

10. Microorganisms (including viruses)

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

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

Permit Conditions: Standard laboratory microorganisms Page 27

11. Human fluids and tissues

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

Country of export: Various countries Various countries

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Permit Conditions:	Human fluids and tissues that are not known to be infected	Page 29
12. Genetic material End use: Country of export:	In vitro use or in vivo use in laboratory organisms Various countries	
Country of origin: Permit Conditions:	Various countries Low risk genetic material and vectors	Page 31
13. Genetic material End use: Country of export: Country of origin: Permit Conditions:	In vitro use or in vivo use in laboratory organisms Various countries Various countries Genetic material purified and derived from standard laboratory microorganisms including viruses	Page 33
14. Antibodies End use: Country of export: Country of origin: Permit Conditions:	In vitro use or in vivo use in laboratory organisms Various countries Various countries Antibodies purified and raised against synthetic material or antigens from multicellular organisms	Page 35
15. Antibodies End use: Country of export: Country of origin: Permit Conditions:	In vitro use or in vivo use in laboratory organisms Various countries Various countries Antibodies purified and raised against microorganisms and viruses	Page 37

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

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

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# Important information about this permit and the import of goods

Note: This permit covers Department of Agriculture and Water Resources 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 Immigration and Border Protection, the Department of Health, Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, the Department of the Environment, 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 and Water Resources 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 when the goods are presented for clearance.

The importer must verify that an import permit has been issued in relation to the consignment by one of the following means:

i. The positive identification of the import permit to the Department of Agriculture and Water Resources at the time that the goods are being processed for biosecurity clearance, such as by presenting the import permit.

OR

 Any form of physical, digital or verbal correspondence presented with information that allows an import permit to be identified.

#### Provision of required documentation

All required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to the Department of Agriculture and Water Resources 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 and Water Resources". 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.

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

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## **Permit conditions**

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

# 1. Purified/refined laboratory reagents

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

1. Purified or refined laboratory reagents

# 1.1. Biosecurity Pathway

#### a. Conditions of Administration

- 1. Documents must be provided with each consignment which:
  - 1.1. identify the consignment e.g. entry number.
  - 1.2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest.
  - 1.3. describe the goods being imported (where not clear). Example 1: Product XRab = Purified protein derived from rabbits. Example 2: Product AX = Synthetic antibiotic. Example 3: Comte = Cheese.
- 2. For further information please contact:

Regional - Clearance assistance:

http://www.agriculture.gov.au/about/contactus/phone/regional

Canberra - Administrative assistance or technical assistance: email imports@agriculture.gov.au (See Attachments) or phone 1800 900 090



If an import permit is required, it is the importer's responsibility to provide any additional information which is requested in order to demonstrate that the import permit covers all goods being imported.

#### b. These conditions allow for the import of:

#### 1. Purified and animal derived:

- 1.1 albumins, including bovine serum albumin
- 1.2 carboxylic acids
- 1.3 co-factors
- 1.4 enzymes
- 1.5 enzyme inhibitors
- 1.6 growth factors
- 1.7 hormones
- 1.8 lipids (this includes fats, waxes, sterols, fat-soluble vitamins (e.g. A, D, E, and K), glycerides, phospholipids and their derivatives.)
- 1.9 molecules (excluding genetic material)
- 1.10 proteins (this includes derivatives e.g. peptides, amino acids). This case does not allow the import of prions.
- 1.11 vitamins.

#### 2. Fermented and then purified:

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2.1 laboratory material derived from a fermentation process e.g. antibiotics and enzymes (it is the importers responsibility to provide documentation to support this claim).

### 3. Purified and bacterial (including recombinant bacterial) and/or fungi derived:

- 3.1 antibiotics (e.g. antibiotic sensitivity discs)
- 3.2 enzymes (e.g. polymerases, modifying enzymes and restriction enzymes)
- 3.3 growth factors
- 3.4 hormones
- 3.5 lipids (this includes fats, waxes, sterols, fat-soluble vitamins (e.g. A, D, E, and K), glycerides, phospholipids and their derivatives.)
- 3.6 molecules (excluding genetic material)
- 3.7 proteins (this includes derivatives e.g. peptides, amino acids). This case does not allow the import of prions.
- c. The products must be imported in quantities of no greater than 20 ml or 20 g 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.

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:

- International (e.g. <u>International Air Transport Association</u>) and domestic requirements concerning the safe handling, transport and labelling of biological material
- 2. AS/NZS 2243 Safety in Laboratories standards
- 3. Office of the Gene Technology Regulator (OGTR) requirements.
- e. Under the <u>Biosecurity Charges Imposition (General) Regulation 2016</u> and Chapter 9, Part 2 of the <u>Biosecurity Regulation 2016</u>, fees are payable to the Department of Agriculture and Water Resources for all services. Detail on how the department applies fees and levies may be found in the charging guidelines.
- f. Non-commodity information requirements for imported cargo also apply, please refer to the BICON case Non-Commodity Cargo Clearance.

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Timber packaging, pallets or dunnage associated with the consignment may be subject to inspection and treatment on arrival, unless sufficient evidence of a Department of Agriculture and Water Resources approved treatment is provided.

All documentation presented to the department to assist in determining the level of biosecurity risk posed by transportation pathways and packaging must also meet the requirements of the non-commodity case.