



Australian Government

Department of Agriculture, Fisheries and Forestry  
Australian Quarantine and Inspection Service

Quarantine Act 1908 Section 13(2AA)

Phone: 02 6272 4578  
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File Ref: 09/01541

# Permit to Import Quarantine Material

Permit: **IP09002963**

Valid From: **23 Sep 2008**

Valid To: **23 Sep 2010**

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Importer	Exporter
SydPath St Vincent's Hospital, Victoria St Darlinghurst NSW 2010 Attn: Lilian Milis	Various Suppliers Exporters Various Addresses In All countries

**You are authorised to import the following material under the listed conditions**  
*Note: This permit covers AQIS quarantine requirement only.*  
 All imports may be subject to quarantine 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 seizure, treatment, re-export or destruction at the importer's expense.  
 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 to ensure it has complied with, all requirements of any other regulatory organisations and advisory bodies prior to and after importation including The Australian Customs Service, The Department of Health and Ageing, Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, Department of the Environment, Water, Heritage and the Arts, 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.

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

Notification of the import must be provided to AQIS 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 *Quarantine Regulations 2000* (examples include a Quarantine Entry or a Quarantine declaration).

Commodity Name	Condition Number(s)	Country	End Use
<b>Sera, blood, fluid or tissue samples (Sourced from all species (excluding salmonid fish, non-human primates, avians, ovines, caprines, bovines, cervines, equines or porcines))</b>	PC0992 AND PC0701	All countries	In-vitro
<b>Sera, blood, fluid or tissue samples (Sourced from ovines, caprines, bovines or cervines only)</b>	PC0992 AND PC0701 AND (PC1649 OR PC0506)	All countries	In-vitro
<b>Sera, blood, fluid or tissue samples (Sourced from equines only)</b>	PC0992 AND PC0701 AND (PC1650 OR PC0506)	All countries	In-vitro

This permit is granted subject to the condition that fees determined under Section 86E are paid

  Delegate of Director of Quarantine <b>Printed Name</b> Sarah Newick	Stamp: 
<b>Date</b> 23 Sep 2008	

Commodity Name	Condition Number(s)	Country	End Use
<b>Antibodies (purified &amp; raised against synthetic material or against antigens derived from multicellular organisms)</b>	PC0992 AND PC0701	All countries	In-vitro
<b>Diagnostic Kits (Diagnostic kits, reagents, standards or components testing for micro-organisms excluding those listed in PCt970)</b>	PCT0970 AND PC0714 AND PC0600 AND PC0992	All countries	In-vitro
<b>Microorganisms (Pseudomonas aeruginosa)</b>	PC0691	All countries	In-vitro

Condition	Condition Text
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PC0506 POST ENTRY REQUIREMENTS

1. Prior to release from Quarantine the material must be subjected to gamma irradiation at 50 kGy (5 Mrad). Irradiation at 50 kGy at an AQIS approved facility is mandatory even if the product has been irradiated prior to import into Australia.

PC0600 PACKING REQUIREMENTS

1. The product must be commercially prepared and packaged

PC0691 1. Each consignment must be accompanied by a valid Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation. Alternatively, necessary documentation will need to be presented to AQIS 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 Quarantine'. Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

### Documentation Requirements

2. Each consignment must be clearly identified and linked to the relevant item(s) on the Import Permit. Identifying documentation must be available to the quarantine officer at the time of clearance. This documentation may include:

- a) an accompanying invoice or airway bill; or
- b) the physical labelling of the goods; or
- c) an overseas supplier's declaration describing the goods.

3. 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 quarantine officer that the Import Permit covers the products in the consignment.

### Packaging Requirements

Condition	Condition Text
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4. Cultures must be pure cultures (unless otherwise specified by this Import Permit) and labelled with the scientific name of the organism.

### Post Entry Requirements

5. This Import Permit allows for the importation of goods for in vitro laboratory studies (or in vivo use in laboratory organisms only), unless approved by AQIS for specific in vivo use in non-laboratory organisms.

6. Laboratory organisms include those defined in the following list and must be contained under laboratory or animal house conditions (or equivalent): guinea pigs, hamsters, mice, rabbits, rats, rodents or micro-organisms. Work in all other animals and plants is not permitted.

7. For in vivo use in non-laboratory organisms (e.g. chickens, sheep, cattle, etc.) or plants a separate application for in vivo use must be lodged with, and approved by AQIS. This also applies if the product is to be used in veterinary vaccine or veterinary therapeutic manufacture.

8. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243 Safety in Laboratory standards Part 3: Microbiology. This includes handling and disposal procedures.

9. It is the importer's responsibility to ensure compliance with all international (e.g. IATA) and domestic requirements concerning the safe handling, transport and labelling of biological material.

10. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the Office of the Gene Technology Regulator (OGTR) requirements.

### PC0701 PACKAGING REQUIREMENTS

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

PC0714 1. A valid copy of this Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to AQIS 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 Quarantine". Documentation may include Import Permit (or Import Permit number), manufacturer's declaration and invoice. The importer must meet all costs associated with the importation of this product.

### DECLARATION REQUIREMENT

2. Each consignment must be accompanied by a manufacturer's declaration, stating:

a) The product does not contain live or whole inactivated viruses, bacteria or any other microorganisms.

The manufacturer's declaration must be:

- . from the manufacturer
- . on manufacturer's letterhead (including company address and country).

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	<ul style="list-style-type: none"> <li>. signed by a senior company employee from the site of manufacture whose name, title and contact details also appear.</li> <li>. dated and free from erasures and uncertified alterations (all alterations must be initialled by the senior company employee responsible for signing the declaration).</li> <li>. written in English and containing the correct statement/s as required above.</li> <li>. specific to the relevant commodity listed on this permit</li> <li>. specific to the consignment by referring to at least one of the following: container number, bill of lading number, commercial invoice number, preferential tariff certificate number, packing list number, letter of credit number, batch/serial number or date of manufacture.</li> </ul>

PC0992 1. A valid copy of this Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to AQIS 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 Quarantine". Documentation may include Import Permit (or Import Permit number), and invoice.

#### DOCUMENTATION REQUIREMENTS

2. Each consignment must be clearly identified and linked to the relevant item(s) on the Import Permit. Identifying documentation must be available to the quarantine officer at the time of clearance. This documentation may include:
  - a) an accompanying invoice or airway bill; or
  - b) the physical labelling of the goods; or
  - c) an overseas supplier's declaration describing the goods.
3. 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 quarantine officer that the Import Permit covers the products in the consignment.
4. Providing all documentation is in order at the time of clearance, the consignment can be released from quarantine.

#### POST ENTRY / END USE CONDITIONS

5. This Import Permit allows for the importation of goods for in vitro laboratory studies (or in vivo use in laboratory organisms only), unless approved by AQIS for specific in vivo use in non-laboratory organisms.
6. This Import Permit does not permit the use of the samples for microbiological cultures or viral isolation, without prior written approval from AQIS.
7. Laboratory organisms include those defined in the following list and must be contained under laboratory or animal house conditions (or equivalent): guinea pigs, hamsters, mice, rabbits, rats, rodents or micro-organisms. Work in all other animals and plants is not permitted.
8. For in vivo use in non-laboratory organisms (eg. chickens, sheep, cattle, etc.) or plants a separate application for in vivo use must be lodged with, and approved by AQIS. This also applies if the

Condition	Condition Text
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product is to be used in veterinary vaccine or veterinary therapeutic manufacture.

9. This Import Permit does not permit the direct or indirect exposure of the imported materials or derivatives to non-laboratory organisms or plants.

10. 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.

11. It is the importer's responsibility to ensure compliance with all international (eg IATA) and domestic requirements concerning the safe handling, transport and labelling of biological material.

12. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243 Safety in Laboratory standards and Office of Gene Technology Regulator (OGTR) requirements.

**PC1649 Sourcing Requirements**

The product must be either sourced from one of the following countries or be irradiated as per PC0506;

Australia, Austria, Belgium, British Honduras, British Virgin Islands, Canada, Chile, Cook Islands, Denmark, Falklands Island, Fiji, France, Finland, French Polynesia, Germany, Greenland, Republic of Ireland, Italy, Luxembourg, Iceland, Malta, Mauritius, Mexico, New Caledonia, New Zealand, Norway, Papua New Guinea, Portugal, Singapore, Spain, Sweden, Switzerland, United Kingdom (excluding products sourced after 1 July 2007 and before 19 February 2008), United States of America, Vanuatu.

**PC1650 Sourcing Requirements**

The product must be either sourced from one of the following countries or be irradiated as per PC0506:

Argentina, Australia, Austria, Belgium, British Honduras, British Virgin Islands, Canada, Chile, Cook Islands, Cyprus, Denmark, Fiji, Finland, France, French Polynesia, Germany, Greece, Greenland, Holland, Iceland, Republic of Ireland, Israel, Italy, Japan, Peoples Republic of Korea, Luxembourg, Malaysia, Malta, Mauritius, Mexico, New Caledonia, New Zealand, Norway, Papua New Guinea, Portugal, Singapore, Spain, Sweden, Switzerland, United Kingdom, United States of America, Vanuatu, Falkland Islands.

End of Condition Text
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**AQIS PERMIT CERTIFICATE PCt970**

**Diagnostic kits, reagents, standards or components testing for the following micro-organisms may not be imported using this import permit.**

- Micro-organisms associated with Quarantinable diseases of humans listed in Table 9 of *Quarantine Proclamation 1998*
  - Cholera (*Vibrio Cholerae*)
  - Plague (*Yersinia pestis*)
  - Rabies (*Lyssavirus*)
  - Severe Acute Respiratory Syndrome (SARS) (SARS associated Coronavirus)
  - Smallpox (*Variola virus* and *Poxvirus variola*)
  - Viral haemorrhagic fevers of humans including Ebola haemorrhagic fever (*Filoviridae*), Marburg virus (*Filoviridae*), Lassa Fever (*Arenaviridae*) and Crimean-Congo hemorrhagic fever (*Nairovirus*)
  - Yellow fever (*Flavivirus*)
  - Highly Pathogenic Avian Influenza in Humans
- Foot and mouth disease virus
- Rinderpest virus
- African horse sickness virus
- Peste des petits ruminants virus
- Ovine and caprine pox virus
- Pulmonary adenomatosis virus
- Swine vesicular disease virus
- African swine fever virus
- Classical swine fever virus
- Avian influenza virus
- Newcastle disease virus