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

Phone: 02 6272 4578
Fax: 02 6249 1798
File Ref: 2010/09588

Quarantine Act 1908 Section 13(2AA)

Permit to Import Quarantine Material

Permit: IP10012358 **Valid From:** 17 Aug 2010 **Valid To:** 17 Aug 2012

Importer	Exporter
WHO Collaborating Centre for Reference and Research on Influenza C/- Melbourne Health Vidrl QAP No V1808,V1811, V1812 10 Wreckyn Street North Melbourne VIC 3051 Attn: Katie O'Brien	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.

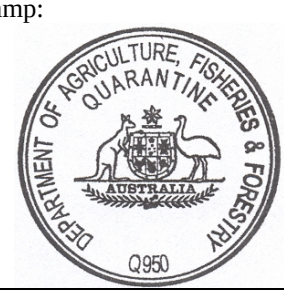
Notification of the import must be provided to AQIS for all imported goods other than goods imported as accompanied baggage or goods imported via the mail and not prescribed under the *Customs Act 1901*. Notification must be consistent with *Quarantine Regulations 2000* (examples include a Quarantine Entry or a Quarantine declaration).

Commodity Name	Condition Number(s)	Country	End Use
Microorganisms (Human influenza isolates and clinical samples as described in PC1672)	PC1672	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
Printed Name Shona Hodgetts **Date** 17 Aug 2010

Stamp:



Commodity Name	Condition Number(s)	Country	End Use
Microorganisms (Modified influenza viruses of either human or avian origin reassorted with PR8 or WSN strains of human influenza virus excluding avian influenza H7 and H5 subtypes)	PC0714 AND PC0600	All countries	In-vitro

Condition	Condition Text
PC0600	This condition requires product to be directed to and held at a Quarantine Approved Premises. 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. 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 4. Cultures must be pure cultures and labelled with the scientific name of the organism. Post Entry Requirements 5. The micro-organisms are for use at: CSL Limited (#V0279) 45 POPLAR ROAD PARKVILLE VIC 3052 AND VIDRL (#V1811, V1812, V1808) 10 WRECKYN STREET NORTH MELBOURNE VIC 3051

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Condition	Condition Text
	6. The goods and their derivatives shall not be removed from these premises, except for disposal or re-export, without the prior approval of the Director of Quarantine. These premises must have current approval, at the time of importation, of the Australian Quarantine and Inspection Service, under Section 46A of the Quarantine Act 1908. The premises must be approved as a Class 5 Quarantine Approved Premises. 7. The level of containment must be QC (PC) 2 or the level stated in Australian Standards AS 2243.3, Safety in Laboratories, Part 3: Microbiology (2002), which ever is the greater level of containment. 8. The level of containment and management practices must also be equivalent to or greater than Biosafety Level 2 enhanced or PC2 enhanced as recommended by the "WHO biosafety risk assessment and guidelines for the production and quality control of human influenza pandemic vaccines, Annex 5". 9. Class 2 biological safety cabinets are to be used for all manipulations that may cause splashes, droplets or aerosols. 10. Work must be limited to in vitro laboratory studies and in vivo use in laboratory organisms and ferrets only, unless approved by AQIS for specific in vivo use in non-laboratory organisms. 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. 11. Work in non-laboratory animals (including vaccine or therapeutic manufacture), or plants is not permitted without prior written approval from AQIS. 12. Where more than one Quarantine Approved Premises is listed in point 5 above, the samples may be transferred between the listed premises. All records of transfer must be maintained for audit purposes. 13. Direct or indirect exposure of native or domestic animals or plants to the materials or their derivatives is prohibited. 14. On completion of work all imported materials and the direct or indirect derivatives thereof shall be disposed of by incineration, autoclaving or other methods approved in writing by the Director of Quarantine. 15. 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. 16. 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 the Gene Technology Regulator (OGTR) requirements.
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.

Condition	Condition Text

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:

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) that the product is a modified influenza virus of either human or avian origin produced through reassortment with the human influenza strain PR8 or WSN and contains at least six internal gene protein segments of PR8 virus and modified HA segment of the avian virus; and

b) that the modified virus has been assessed and found negative for pathogenicity in the statutory chicken intravenous test (IVP index of 1.2 or less, OIE 2000 4th edition or equivalent pathogenicity testing) in chickens.

The manufacturer's declaration must be:
.from The Manufacturer

. where the manufacturer is not specified above, the declaration must be issued by the individual manufacturing site or by the manufacturer's head office within the country of export.
. on manufacturer's letterhead including company address and country.
. written in English.
. signed by a designated representative whose name, position and title also appear.
. identify the date of issue.
. issued and dated within the last 6 months (unless otherwise specified in this import permit).
. free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a company stamp or seal and the signature of the company officer responsible for signing the declaration applied adjacent to the alteration).
. contain the correct statement/s as required by the import conditions (all prescribed information on the certification must be legible and appear above the signature).
. specific to the product(s) listed on this permit.
. have a unique identifiable link to the consignment such as one of the following: container number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number or letter of credit number, batch/serial number or date of manufacture.

All documentation must meet the requirements of the Minimum Documentary Requirements Policy. For full details of the AQIS minimum documentary requirements, please refer to http://www.daff.gov.au/aqis/import/general-info/documentary-requirements.

Condition	Condition Text

PC1672 This condition requires product to be directed to and held at a Quarantine Approved Premise (QAP).

1. This permit allows import only of:

a) Influenza viral isolates of human origin Types A, B and C, excluding avian influenza H7 and H5 subtypes; and

b) Clinical samples from humans not suspected of being infected with avian influenza viruses.

2. All consignments 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 must 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. The importer must meet all costs associated with the importation of this product.

DOCUMENTATION REQUIREMENTS
3. 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.

4. 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 REQUIREMENT
5. Consignments must be packaged in accordance with International Air Transport Association (IATA) Packing Instructions 602 or 650 requiring watertight primary receptacle(s) to be packaged inside a watertight secondary package.

POST ENTRY REQUIREMENTS
6. The products are for use at:

Melbourne Health (#V1808)
VIDRL, Level 2, 10 Wreckyn Street
NORTH MELBOURNE
VIC
3051

Melbourne Health (#V1811)
VIDRL, Level 1, 10 Wreckyn Street
NORTH MELBOURNE
VIC
3051

Condition	Condition Text

Melbourne Health (#V1812)
VIDRL, Rm, 2.45, Level 2, 10 Wreckyn Street
NORTH MELBOURNE
VIC
3051

CSL Limited (#V0279)
45 POPLAR ROAD
PARKVILLE
VIC
3052

7. These premises must have current approval, at the time of importation, of the Australian Quarantine and Inspection Service, under Section 46A of the Quarantine Act 1908. The premises must be approved as a Class 5 Quarantine Approved Premises and the level of containment must be QC (PC) 2.

8. All work must be conducted in Class 2 Biologicals Safety Cabinets.

9. Biosafety Level 3 precautions must be adopted and followed while working with influenza A subtypes isolated from clinical samples as recommended by the WHO laboratory biosafety guidelines for handling specimens suspected of containing avian influenza A virus 12 January 2005.

10. This Import Permit allows for the importation of goods for in vitro laboratory studies and in vivo use in laboratory organisms and ferrets only, unless approved by AQIS for specific in vivo use in non-laboratory organisms.

11. 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 are not permitted.

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

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

14. 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 the Gene Technology Regulator (OGTR) requirements.

15. On completion of work all imported materials and the direct or indirect derivatives thereof shall be disposed of by incineration or autoclaving.

16. The only goods and their derivatives that may be removed from these premises, except for disposal or re-export, without the prior approval of the Director of Quarantine, are Influenza isolates that have been typed as human influenza virus (A, B or C) and shown not to be derived from avian influenza viruses. These isolates may be transferred from QAP # V0279 at CSL Limited, 45 Poplar Rd. Parkville to other laboratories including laboratories that are not registered

Condition	Condition Text

as a QAP providing all other post entry requirements are met. The importer must have on file a letter from recipient laboratories confirming the following:

a) the laboratory has PC2 level containment facilities
b) the laboratory will follow PC3 level precautions while working with the isolates.
c) all work with the isolates will be conducted in Class 2 Biologicals Safety Cabinets
d) on completion of work all isolates will be disposed of by incineration or autoclaving
e) Biosafety Level 3 precautions are adopted and followed while working with influenza A subtypes as recommended by the WHO laboratory biosafety guidelines for handling specimens suspected of containing avian influenza A virus 12 January 2005
The letters from recipient laboratories must be made available to AQIS on request for auditing purposes.

17. It is the importer's responsibility to ensure that the goods are labelled "in vitro use only" or "restricted end use" on the smallest packaged unit and "in vitro use and in vivo use in laboratory animals only" on the secondary packaging unit prior to distribution.

18. 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.

End of Condition Text

Delegate of Director of Quarantine
Printed Name Shona Hodgetts **Date** 17 Aug 2010