Purified antibodies raised against inorganic material or against antigens from multicellular organisms (Standard Permit)

Import Requirements

a. Prior to the importation of goods into Australian territory, a valid import permit issued by the Department of Agriculture, Water and the Environment is required.

An import permit may be obtained by submitting an import permit application to the department (use the 'Apply Now' button at the bottom of this page).

If the import conditions cannot be met then a permit application for a non-standard commodity will be required. Note: additional information (e.g. product names, approved arrangement sites) will not be considered during permit assessment or included in the standard permit conditions.

To apply you must logon to BICON and complete an application for Antibodies

> Processing officer note: If goods arrive in Australian territory without a valid import permit please refer to the procedure *Managing conditionally non-prohibited goods arriving without an import permit* which can be found in the 'Procedures and Work Instructions' tab.

b. These conditions allow for the import of purified antibodies raised against either:

1. multicellular organisms (or parts of multicellular organisms), excluding fungi, that are not genetically-modified and have not been deliberately infected with a disease agent, and are not known to be infected with a disease agent*,
2. inorganic or chemically-synthesised material, excluding material encoding whole genome segments of any virus or viroid. Inorganic means not consisting of or deriving from any living matter, virus or viroid.

c. The antibodies must not be suspended in whole blood, sera, plasma, ascitic fluid or culture supernatant fluid.

d. The antibodies must not be raised against any prion (whether naturally occurring, chemically synthesized or recombinant protein) from any species.

e. The antibodies may be conjugated to chemical compounds or radioactive isotopes, and/or may be bound to an inorganic solid structure.

f. The goods are individually packaged in units of no greater than 20mL or 20g.

g. 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:

1. The name of each antibody; and
2. The name of the antigen each antibody is raised against (including the common and/or scientific name of the multicellular organism, or name of the non-biological/chemically-synthesized material); and
3. A statement that the antibody/ies are raised against:
    i. multicellular organisms (or parts of multicellular organisms), excluding fungi, that are not genetically-modified and have not been deliberately infected with a disease agent, and are not known to be infected with a disease agent; or
    ii. inorganic or chemically-synthesised material, excluding material encoding whole genome segments of any virus or viroid; and

4. A statement that the antibody/ies were not raised against any prions (whether naturally-occurring, chemically-synthesized or recombinant protein)

h. **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@awe.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
4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

i. **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.

j. 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, Water and the Environment for all services. Detail on how the department applies fees and levies may be found in the Charging guidelines.

k. 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.

If you are unable to meet the declaration requirements or you would like the specific product names listed on the permit, please select the 'Previous' button at the bottom of this page and change your answer to 'Submit non-standard permit application'.