

# Genetic material derived from multicellular organisms (Standard Permit)

## 1. Biosecurity Pathway

#### Import conditions prior to arrival in Australian territory

- a. These conditions allow for the importation of:
  - 1. Purified genetic material (nucleic acids) derived from multicellular organisms (excluding plants and fungi);

or

- 2. Purified standard laboratory cloning vectors and expression systems described in point 2.1 below that contain transgenes (the specific gene of interest) derived from multicellular organisms (excluding plants and fungi) only.
  - 2.1.Permitted purified standard laboratory cloning and expression vectors are:
    - 2.1.1. Plasmids, cosmids, yeast and bacterial artificial chromosomes, which have been deliberately constructed for that purpose which are non-integrative and non-conjugative, and do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions, or which contain known autonomous genetic elements from any species, or "pathogenicity islands" or known bacterial virulence factors excluding antimicrobial resistance genes used to facilitate selection and plasmid replication factors; and
    - 2.1.2. Human immunodeficiency virus (HIV) vectors, bacteriophages lambda, lambdoid and Ff, polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV). No other viral vectors are permitted; and
    - 2.1.3. Escherichia coli-Streptomyces artificial chromosome (ESAC) vectors.
- b. These conditions do NOT allow the importation of:
  - 1. Genetic material derived from microorganisms and infectious agents (including prions).
  - 2. Cloning vectors or expression systems that contain transgenes (the specific gene of interest) derived from or homologous to sequences from microorganisms and infectious agents (including prions).
  - 3. Genetic material derived from plants.
  - 4. Genetic material derived from fungi.
- c. The goods are individually packaged in units of no greater than 20mL or 20g.
- d. 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:

#### Evidence that:

- 1. The genetic material is highly purified and unable to replicate; and
- 2. The genetic material is derived from multicellular organisms (excluding plants, fungi or prions from any species) only; and

For goods containing cloning and expression vectors:

- 3. The cloning and expression vector is one of the following:
  - 3.1.Plasmids, cosmids, yeast and bacterial artificial chromosomes, which have been deliberately constructed for that purpose which are non-integrative and non-conjugative, and do not contain nucleic acid sequences which encode for regions able to restore or introduce integrative and conjugative functions, or which contain known autonomous genetic elements from any species, or "pathogenicity islands" or known bacterial virulence factors excluding antimicrobial resistance genes used to facilitate selection and plasmid replication factors; or
  - 3.2. Human immunodeficiency virus (HIV) vectors, bacteriophages lambda, lambdoid and Ff, polyhedrin negative strains of Autographa californica nuclear polyhedrosis virus (AcNPV) and polyhedrin negative strains of Bombyx mori nucleopolyhedrosis virus (BmNPV); or
  - 3.3. Escherichia coli-Streptomyces artificial chromosome (ESAC) vectors.

### e. 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 <a href="mailto:imports@awe.gov.au">imports@awe.gov.au</a> 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. <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
- 4. The Security Sensitive Biological Agents (SSBA) regulatory scheme.