Genetic material derived from or homologous to sequences from disease agents (Standard Permit)

1. Biosecurity Pathway

Import conditions prior to arrival in Australian territory

a. These conditions allow for the import of purified genetic material derived from, or homologous to sequences from, disease agents* excluding:

1. Pathogens of animal biosecurity concern for biological products, as published on the Department of Agriculture, Fisheries and Forestry's website; and
2. Disease agents causing Listed Human Diseases, as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*; and
3. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

*Disease agent includes but is not limited to microorganism, parasite, virus, prion, plasmid or viroid.

b. The genetic material may be imported in the following purified standard laboratory cloning vectors and expression systems:

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. 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
3. *Escherichia coli-Streptomyces* artificial chromosome (ESAC) vectors.

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

d. The genetic material must not be derived from or homologous to sequences from any prion (whether naturally occurring, chemically synthesized or recombinant protein).

e. 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 has been highly purified and is unable to replicate, and
2. The genetic material is derived or homologous to sequences from disease agents, excluding pathogens of animal biosecurity concern for biological products (as published on the Department of Agriculture, Fisheries and Forestry's website), a disease agent causing a Listed Human Disease (as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human*

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Diseases) Determination 2016) or plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

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.

f. **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 importer's 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.

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