

Information for Importers of Biological Products, Micro-organisms and Cell Cultures

What are the import health standards (IHSs) for biological products of animal origin?

Biological products of animal origin, cell cultures and microorganisms fall under the following IHSs:

- Biological Products (including samples) [BIOPRODIC.ALL](#)
- Cell Cultures from All Countries [CELLCULIC.ALL](#)
- Microorganisms from All Countries [MICROIC.ALL](#)

Items falling under the scope of these standards may be eligible for import with either a general or restricted permit, or in some cases are eligible for clearance with no permit to import, depending on the commodity:

- A general permit to import has no post entry conditions placed on the items being imported, where the items on the permit have been assessed as posing a minimal risk to New Zealand's biosecurity.
- A restricted permit to import has post entry conditions placed on the items being imported. The items on a restricted permit must go into either a transitional or containment facility based on the assessed risk they pose to the biosecurity of New Zealand.

Which import health standard should I use?

Biological products are **non-viable** (that is, they are dead/not living) products derived from living organisms, including samples of animal origin (excluding humans).

IHS for Biological Products (including samples) – [BIOPRODIC.ALL](#)

The following can be imported:

- ✓ Non-viable items for laboratory research, diagnostic and analytical purposes (including equipment calibration and validation)
- ✓ Animal product samples for evaluation and/or proficiency testing (for example: dairy, meat and skin samples)
 - Only samples from healthy animals may be imported under this IHS.
 - No samples from animals suspected of carrying infectious disease agents may be imported under this IHS.
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- ✓ Items for environmental use that are commercially manufactured and packaged products (for example: effluent biodegraders containing enzymes).

- ✓ Items intended for use in/on humans, animals and/or plants for medical, veterinary or horticultural use.

Cell cultures and microorganisms

To import items that are, or contain, viable microorganisms or viable cell cultures / non-microbial cells you will need to apply for a permit to import under CELLCULIC.ALL or MICROIC.ALL. This includes animal product samples where micro-organisms culture or isolation will be attempted (e.g. meat or dairy samples for food safety micro-organism culture).

IHS for Cell Cultures from All Countries – [CELLCULIC.ALL](#)

Goods that are, or contain, viable cell cultures/non-microbial cells must be imported under CELLCULIC.ALL. This includes items that are imported with the intention of cell isolation and/or culture and also where the cultures/non-microbial cells may, or may not be, rendered non-viable as part of the processing.

Examples include, but are not limited to,:

- ✓ Cell cultures
- ✓ Cell lines
- ✓ Non-microbial cells
- ✓ Cell cultures derived from humans that are genetically modified or are new organisms (as defined by the HSNO Act)
- ✓ Cell cultures derived from tissues of unwanted organisms

To note:

- Cell cultures / cell lines derived from non-new organisms must be imported into a **transitional facility** approved to the MPI / EPA Standard [Facilities for Microorganisms and Cell Cultures: 2007a](#) (154.03.02)
- Cell cultures / cell lines derived from **new organisms** must be imported into a **containment facility** approved to the MPI / EPA Standard [Facilities for Microorganisms and Cell Cultures: 2007a](#) (154.03.02). You must also adhere to the conditions set out in the **Hazardous Substances and New Organism (HSNO) Act approval number** noted on the permit to import.

IHS for Microorganisms from All Countries – [MICROIC.ALL](#)

Goods that are, or contain, viable micro-organisms (for example: *Escherichia coli*, *Lactobacillus acidophilus*) must be imported under MICROIC.ALL. This includes products imported with the intention of micro-organism enrichment (e.g. prions), isolation, and/or culture and products containing microorganisms which may, or may not be, rendered non-viable as part of the processing.

Examples include, but are not limited to,:

- ✓ Protozoa

- ✓ Fungi
- ✓ Bacteria
- ✓ Viruses
- ✓ Unicellular algae
- ✓ Prions
- ✓ Animal product sample that will be cultured to isolate micro-organisms

To note:

- Microorganisms that are not new / not unwanted organisms have **no** post entry requirements and will be listed on a general permit to import.
- Unwanted organisms with a Ministry for Primary Industries (MPI) Chief Technical Officer (CTO) approval under sections 52 and 53 of the Biosecurity Act 1993 must be imported into a **containment facility** (if it is a new organism, there will also be the requirement to gain approval under the HSNO Act). The containment facility must be approved to the MPI / EPA Standard [Facilities for Microorganisms and Cell Cultures: 2007a](#) (154.03.02).
- New organisms with HSNO Act approval from Environmental Protection Authority (EPA) New Zealand must be imported into a **containment facility** (if it is also an unwanted organism it will also need to be accompanied by a MPI CTO approval under sections 52 and 53 of the Biosecurity Act 1993). The containment facility must be approved to the MPI / EPA Standard [Facilities for Microorganisms and Cell Cultures: 2007a](#) (154.03.02).
- If you intend to culture unknown micro-organisms from an imported biological product, (e.g a sample of a meat or dairy product for food safety microbiological analysis) you will need to have an appropriate approval from the EPA as these samples potentially contain organisms new to New Zealand.

What if I want to import an unwanted, new or genetically modified organism?

When importing viable organisms, you must check that the organisms have been deemed to be present in New Zealand by the EPA and that they are not unwanted organisms or regulated. This is to make sure any potential or perceived biosecurity risk to New Zealand is managed in an appropriate manner.

Check the following websites:

- HSNO Act application register (<http://www.epa.govt.nz/search-databases/Pages/applications-search.aspx>)
 - If you cannot find the listing for the organism you want to import, contact the EPA (neworganisms@epa.govt.nz)
- Unwanted Organisms register (<http://www1.maf.govt.nz/uor/searchframe.htm>)

- Biosecurity Organisms Register for Imported Commodities – BORIC (<http://www.maf.govt.nz/biosecurity-animal-welfare/pests-diseases/boric.aspx>)

HSNO Act approvals

What do the approval codes mean?

- Approval codes that begin with **BER** or **PNZ** mean that the organism is present in New Zealand.
- Approval codes that begin with **S26** mean that the organism has been determined to not be a new organism.
- Approval codes that begin with **NOC** or **GMC** mean that the organism has post entry requirements if they are imported and will need to go into a containment facility.
 - NOC stands for New Organism Containment
 - GMC stands for Genetically Modified Containment
- Approval codes that begin with **GMD** are organisms that are only allowed domestic development in New Zealand and are not able to be imported under this particular approval code.
 - GMD stands for Genetically Modified Development

When do I need a HSNO Act approval if organism identification is being undertaken?

In advice received from the EPA:

- If unidentified cultures are being imported for identification, and there is the potential for new organisms to be present, then a HSNO Act approval is required.
- If samples are being imported with the intention of isolating, growing and then identifying organisms, and there is the potential for new organisms to be present, then a HSNO Act approval is required.
- If samples are being imported with the intention of using destructive analytical techniques to identify organisms (e.g. using molecular techniques) and there is no intention to isolate and grow the organism, then a HSNO Act approval is not required. If the purpose of the importation changes and organisms are to be isolated, then point (b) applies and a HSNO Act approval is required.

You may need to contact the EPA to receive advice on whether or not you require a HSNO approval:

Email: neworganisms@epa.govt.nz

Phone: 04 474 5591

Unwanted Organisms

The Biosecurity Act 1993 defines an unwanted organism as any organism a chief technical officer believes capable of causing unwanted harm to any natural and physical resources or human health.

Under sections 52 (communication of a pest or [unwanted] organism) and 53 (duties of owners of organisms) of the Biosecurity Act 1993, you must seek a permission to breed, knowingly communicate,

exhibit, multiply, propagate, release, or sell, an unwanted organism.

An organism can be deemed present in New Zealand by the EPA but can also be classed as an unwanted organism. In order to import an unwanted organism, you must apply for:

- MPI CTO approval to import under sections 52 and 53 of the Biosecurity Act 1993 ('communicate'); and
- a restricted permit to import from MPI. The permit will specify that the product must be directed to an MPI approved containment facility.

It is the responsibility of the applicant to obtain the section 52 / 53 permission (contact MPI for an application form).

In summary ...

- Organisms that have a HSNO approval code that begins with BER, PNZ or S26 and **are not unwanted organisms or regulated in BORIC** can be imported with a general permit to import (organisms that have been deemed to be present in New Zealand by the EPA but which are also unwanted organisms or regulated in BORIC are covered in the above section).
- Organisms that are new or genetically modified and have an appropriate HSNO approval code that begins with NOC or GMC may be imported on a restricted permit to import. These will have post entry conditions including direction to an MPI approved containment facility.
- Organisms that only have a HSNO approval code beginning with GMD are not allowed importation into New Zealand.
- The conditions set out in all HSNO Act approval(s) and/or CTO approval must be adhered to.

Any questions or comments?

If you have any queries or comments relating to BIOPRODIC.ALL, MICROIC.ALL or CELLCULIC.ALL, please don't hesitate to contact Animal Imports at:

Email: animalimports@mpi.govt.nz

Phone: 04 894 0304